VETERANS HEALTH ADMINISTRATION
OFFICE OF PATIENT CARE SERVICES
TECHNOLOGY ASSESSMENT PROGRAM

Brief Overview:

Complementary and Alternative Therapies—Effectiveness of Energy Therapies

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December 2010

TECHNOLOGY ASSESSMENT PROGRAM

An Effective Resource for Evidence-based Managers

VA's Technology Assessment Program (TAP) is a national program within the Office of Patient Care Services dedicated to advancing evidence-based decision making in VA. TAP responds to the information needs of senior VA policy makers by carrying out systematic reviews of the medical literature on health care technologies to determine "what works" in health care. "Technologies" may be devices, drugs, procedures, and organizational and supportive systems used in health care. TAP reports can be used to support better resource management.

TAP provides the *Brief Overview* to help fill the urgent information needs of its VA clients. The *Brief Overview* employs a systematic review methodology to identify and synthesize the best available evidence from the peer-reviewed literature. Content will depend on the availability of information, intended use and desired time frame. It may require some additional reading of documents (provided with the overview for the client) to obtain a full and comprehensive picture of the state of knowledge on the topic.

All TAP products are reviewed internally by TAP's physician advisor and key experts in VA. Additional comments and information on this report can be sent to:

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A SUMMARY FOR HTA REPORTS

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VATAP is a member of the International Network of Agencies for Health Technology Assessment (INAHTA) [www.inahta.org]. INAHTA developed this checklist© as a quality assurance guide to foster consistency and transparency in the health technology assessment (HTA) process. VATAP added this checklist© to its reports in 2002.

This summary form is intended as an aid for those who want to record the extent to which an HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.

Brief Overview:

Complementary and Alternative Therapies—
Effectiveness of Energy Therapies

December 2010

Item	Yes	Partly	No
Preliminary			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?	√		
4. Statement on whether report was externally reviewed?	√		
5. Short summary in non-technical language?			√
Why?			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?	√		
How?			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
What?			
12. Results of assessment clearly presented?	√		
13. Interpretation of assessment results included?	√		
What Then?			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?			√
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?	√		

CONTRIBUTORS TO THIS REVIEW

VATAP projects draw on expertise within VA nationally; physical locations provide contact guidance for contributors.
No contributors to this review report conflicts of interest.

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Elaine Alligood Information Specialist Boston	Literature database searches	Database searches: • Design strategy; • Choose/manage databases; • Strategy text and bibliography for report; • VATAP library/archive of information resources.
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Valerie Lawrence Physician Advisor San Antonio	Content and methods review	Final review: • Internal consistency; • Clarity; • Clinical context; • Methods.
VA Complementary and Alternative Medicine Field Advisory Group	Advisory group	• Design strategy; • General draft content review; • Clarity.

ABBREVIATIONS

ACAOM, Accreditation and Commission for Acupuncture and Oriental Medicine

AD, Alzheimer's Disease

ADL, activities of daily living

AIMS, Abnormal Involuntary Movements Scale

ANOVA, analysis of variance

ATR, atypical response

BAI, Beck Anxiety Inventory

BAP, bone specific alkaline phosphatase

BARDS, Brief Agitation Rating Scale

BAT, behavioral approach task

BCTA/NA, The Biodynamic Craniosacral Therapy Association of North America

BMD, bone mineral content or density

BMI, body mass index

CAB, coronary artery bypass

CAM, complementary and alternative medicine

CAM-FAC, CAM Field Advisory Committee

CCDANCTR, Collaboration Depression, Anxiety and Neurosis Controlled Trials Registers

CCT, controlled clinical trial

CDSR, Cochrane Database for Systematic Reviews

CES-D, Center for Epidemiological Studies-Depression Scale

CHTI, Certified Healing Touch Instructor

CHTP, Certified Healing Touch Practitioner

CI, confidence intervals

CMAI, Cohen-Mansfield Agitation Inventory

CONSORT, Consolidated Standards of Reporting Trials

CQI, continuous quality improvement

CST, craniosacral therapy

DB, deep breathing

DBP, diastolic blood pressure

DH, distant healing

DOE, Department of Education

DSM-IV, Diagnostic and Statistical Manual, 4^{th} edition

EFT, Gary Craig's Emotional Freedom Techniques

ER, emergency room

ERC, enhanced respite control condition

ES, effect size

ES_{sm}, standardized mean difference effect size

FACT, Focus on Alternative and Complementary Therapies

FAHI, Functional Assessment of Human Immunodeficiency Virus

FDA, The US Food and Drug Administration

HAD, Hospital Anxiety and Depression

HADS, Hospital Anxiety and Depression Scale

HAT, Health Attribution Test

HIV/AIDS, Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

HSD, honestly significant difference

HT, healing touch

HTCQ, The Healing Touch Comfort Questionnaire

HTI, Healing Touch International

ICD-10, International Classification of Diseases

INC, inconsistent response

IRR, incidence rate ratio

ITT, intention-to-treat

JCAHO, The Joint Commission on Accreditation of Healthcare Organizations

LOS, length of stay

mABRS, Modified Agitated Behavior

Rating Scale

MD, mean difference

MHCS, Mental Health Component Summary

MMSE, Mini Mental State Examination

MPAC, Memorial Pain Assessment Card

MPQ, McGill Pain Questionnaire

MYMOP, Measure Yourself Medical Outcomes Profile

NANDA, North American Nursing Diagnosis Association

NCBTMB, National Certification Board for Therapeutic Massage & Bodywork

NCCA, National Commission for Certifying Agencies

NCCAM, National Center for Complementary and Alternative Medicine

NCCAOM, National Commission for the Certification of Acupuncture and Oriental medicine

NCTT, non-contact therapeutic touch

NH-PAI, The Nurse Healers-Professional Associates International

NLNAC, National league for Nursing Accrediting Commission

NRS, numerical rating scale

OEMT, Oscillating-Energy Manual Therapy

OR, odds ratio

OT, occupational therapy

PANSS, Positive and Negative Syndrome Scale

PHCS, Physical Health Component Summary

POM, profile of mood

PRIT, Total pain Rating Index

PSQI, Pittsburgh Sleep Quality Index

PSS, Perceived Stress Scale

PSWQ, Penn State Worry Questionnaire

PT, physical therapy

PTSD, post-traumatic stress disorder

PYD, pyridinoline

QoL-AD, Quality of Life-Alzheimer's Disease

RCT, randomized clinical trial

RDS, Roland Disability Index

RFS, Rhoten Fatigue Scale

RL, response level

RN, registered nurse

RNA, ribonucleic acid

RT, resistance training

SBP, systolic blood pressure

SD, standard deviation

SDS, self-directed support

SMD, standard mean difference

STAI, State Trait Anxiety Inventory

SUDS, subjective units of distress

TAP, Technology Assessment Program

TAS, Tellegen Absorption Scale

TAT, Tapas Acupressure Technique

TC, tai chi

TCM, Traditional Chinese Medicine

TFT, Though Field Therapy

TSI, Trauma Symptom inventory

TT, therapeutic touch

TTIA, Therapeutic Touch International Association

UOS, uncontrolled observational studies

USPSTF, US Preventive Services Task Force

VA, Veterans Administration

VAS, Visual Analog Scale

WHOQOL, World Health Organization Quality of Life BREF Version,

WMD, weighted mean difference

WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index

BRIEF OVERVIEW:

Complementary and Alternative Therapies— Effectiveness of Energy Therapies

BACKGROUND

In April of 2010, the VA Complementary and Alternative Medicine Field Advisory Committee (CAM-FAC) requested that the VA Technology Assessment Program (TAP) critically appraise the research evidence for the clinical use of energy therapies in the Veteran population.

This report is one in a series carried out for the CAM-FAC to support guidance on the use of CAM practices in VA and to inform recommendations for credentialing and privileging CAM practitioners in VA.

The two previous evidence reports were on acupuncture (Adams 2007; being updated) and CAM interventions for PTSD (Adams 2010 in press).

DEFINITIONS OF CAM AND ENERGY THERAPY

The National Center for Complementary and Alternative Medicine (NCCAM)[1] defines CAM as follows:[2]

> *"CAM is a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine [as practiced in the United States]."*

NCCAM categorizes CAM practices into four (sometimes overlapping) domains, one of which is energy-based therapy. **Energy therapy** is a broad category of practices based in the belief that there are energy fields in and around the human body that can be manipulated with the intent of maintaining health and assisting the body in healing from illness. There are two classifications of energy therapies: biofield therapies and electromagnetic-based field therapies.

NCCAM categorizes energy therapy as either veritable (measurable) or putative (yet to be measured). Practices based on veritable forms of energy include those involving electromagnetic fields (e.g., **magnet therapy** and **light therapy**). Veritable forms of energy therapies are amenable to research and, therefore, tend to be more accepted in Western medicine.

Putative energy (biofield energy) therapy is based on the belief that all living beings are surrounded or penetrated by energy fields or forces that support life. This force may be known by many names in different cultures, such as *ki* in Japan, as *chi* or *qi* in China, and as *prana* in

[1] NCCAM is the Federal Government's lead agency for scientific research on the diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine. http://nccam.nih.gov/about/ Accessed October 30, 2009.

[2] Source: http://nccam.nih.gov/health/whatiscam/overview.htm Accessed October 30, 2009.

India. Since the presence of putative energy fields has not been scientifically proven, these practices tend to be less accepted in Western medicine.

Biofield energy practices will be the main focus of this review.

WORKING DEFINITIONS AND DESCRIPTIONS

Working definitions of the most common biofield energy practices are presented below. There is considerable overlap in definitions of these practices, reflecting a lack of consensus within the CAM community. In addition, there are often multiple and overlapping synonyms for these terms.

Where available, information regarding organizations accredited by an accrediting agency or state approval agency recognized by the US Department of Education (DOE) will be provided.[3] US DOE recognition means that these organizations are considered reliable authorities regarding the quality of education or training provided by the institutions of higher education and the higher education programs they accredit. US DOE only evaluates accrediting agencies that apply for recognition, so lack of recognition would not necessarily imply an unreliable accrediting body.

Reiki[4]

Reiki is based on the belief that Reiki energy is channeled through the practitioner's hands to heal the person's spirit, which, in turn, heals the physical body. Reiki is administered through a gentle laying on of hands or remotely. It is believed to have origins in ancient Buddhist healing practices. It dates back to 11th Century Japan and was revitalized by Dr. Mikao Usui, a physician and Japanese monk, in the 19th century. Reiki has been available in the United States since the 1970s.

Reiki is taught in three (or sometimes four) levels. To practice Reiki, one must receive a series of "attunements" (initiations) from a Reiki Master, which allows the Reiki energy to flow from the practitioner's hands to the patient. Training for the lower levels typically takes 1 or 2 days and begins with an attunement. Training to become a Master focuses on development of spiritual consciousness and may take years. At the higher levels, one can channel Reiki energy and influence the recipient's well-being at a geographic distance.

Reiki training requires no special background or credentials. Many schools and organizations offer Reiki, but no professional standards exist for Reiki practice. States vary in licensing requirements for the practice of Reiki.

Meditative movement: Qigong, Tai Chi and yoga

Qigong and Tai Chi[5,6]

[3] U.S. Department of Education's Office of Postsecondary Education Database of Accredited Programs and Institutions [http://ope.ed.gov/accreditation/], searched August 11, 2010.
[4] Source: http://www.asunam.com/asunam1.htm, accessed August 9, 2010.
[5] Source: http://www.qigonghealing.com/qigong/whatis.html accessed August 9, 2010.
[6] Source: http://www.instituteofintegralqigongandtaichi.org/ accessed March 11, 2011.

Qigong ("working with the qi") is an ancient mind-body practice originating in China using intention, movement, breathing techniques and meditation believed to influence the flow of life energy (qi). Its purposes are spiritual enlightenment, health improvement and self-defense. Variations of qigong have been incorporated into Traditional Chinese Medicine (TCM) practices used today. Regarding health, Qigong may involve internal and external practices. Internal Qigong is a self-directed approach that involves deep breathing, concentration and relaxation techniques; these techniques may be taught by an instructor. External Qigong (also called Medical Qigong) is performed by a Master laying his or her hands on a patient to direct qi for the purpose of healing.

Originating from Qigong, Tai Chi (also called Tai Chi Chuan, taijiquan) is a traditional Chinese practice that was originally developed as a martial art and as a form of meditative movement. It involves a series of slow, rhythmic, and meditative body movements designed to balance the flow of "chi" around the body and induce relaxation, inner calm, and peace. Tai Chi and Qigong share many similarities, but in general, traditional Tai Chi routines are lengthy, complex and more demanding. Modern Tai Chi practices often are simplified to reduce the number of movements to be learned, thereby increasing their uptake in health promotion in Western cultures. In that respect modern Tai Chi may more closely resemble traditional Qigong.

Many schools and organizations offer varying levels of Tai Chi or Qigong training.[7] Training ranges from informational sessions to didactic and experiential training of 25-200 or more hours for teacher certifications. At these levels, training has not been standardized nor is it subject to state regulation. Graduates in the Master level study of Medical Qigong are eligible to sit for the Medical Qigong exam from the National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM), and, with additional training, may be eligible to become an instructor to train teachers.

Certification in Medical Qigong must be provided by an accredited College of Oriental Medicine, in this case, one accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM). The ACAOM is the only national accrediting agency recognized by the US DOE to accredit Master's-level programs in the acupuncture and Oriental medicine professions.[8] However, in the USA Medical Qigong is not licensed or regulated.

For the purposes of credentialing and licensing VA practitioners of CAM, this report will consider evidence of either Qigong or Tai Chi used to treat specific health conditions.

Yoga[9]

Yoga is believed to originate from the philosophies of ancient India. The practice of yoga involves balancing the body, mind and spirit through gentle stretching poses (asanas), breathing practices (pranayama) and meditation. The underlying principle of yoga is that a blockage or imbalance in life force (prana) in the whole body or in one part of the body leads to a lowered body resistance to disease. Some individuals may apply yoga as a form of physical exercise alone, but integrating all aspects of yoga is believed to create a harmonious internal environment in which the individual can manifest an optimal state of health and well-being.

There are many forms of modern day yoga and an equal array of training opportunities ranging from individual instruction to naturopathic schools to colleges and universities. All yoga forms

[7]Source: http://www.instituteofintegralqigongandtaichi.org/certification/overviewnew.html accessed March 11, 2011
[8]Source: www.acaom.org accessed March 11, 2011
[9]Source: http://www.holisticonline.com/yoga/hol_yoga_home.htm, accessed March 29, 2011.

share common elements, but some, as more typically seen in Western cultures, place more emphasis on postures and breathing while others focus on spirituality.

Currently, there are no federal accreditation requirements or standards for yoga, although state requirements may vary. Yoga Alliance® is the national education and support organization for yoga in the United States.[10] They seek to uphold the standards of yoga history and traditions and quality instruction of teachers. A growing number of yoga training schools are registering with Yoga Alliance®, although it is not a professional requirement.

For the purposes of credentialing and licensing VA practitioners of CAM, evidence of any form of yoga used to treat specific health conditions will be considered.

Therapeutic touch[11]

Therapeutic touch (TT) was developed in the 1970s by Krieger and Kunz. TT is based on the belief that by assessing the patient's energy field, the practitioner can correct any perceived imbalances in energy that may lead to ill health. The most common form of TT requires no physical touching of the patient but rather passing the practitioner's hands a few inches above the patient.

TT consists of four steps:
1. Centering the mind to align the healer with the patient's energy;
2. Assessing the patient's energy field;
3. Clearing the stagnant energy to prepare for energy transfer;
4. Transferring the energy from practitioner to patient.

Although TT was developed primarily for nurses, training is available at many universities, medical schools and professional workshops, as well as nursing schools. "Energy Field Disturbance" is an approved nursing diagnosis of the North American Nursing Diagnosis Association (NANDA), for which TT is the suggested treatment (Taylor 2011). The National League for Nursing Accrediting Commission (NLNAC), recognized by the US Department of Education as the accrediting body for all types of nursing education programs, has produced education materials on TT. However, a growing body of nursing researchers and practitioners has been critical of the evidence for effectiveness of TT.[12] As a result TT is a widely, though not uniformly, accepted healing intervention in the nursing profession.

The Therapeutic Touch International Association, Inc., (TTIA), formerly The Nurse Healers-Professional Associates International (NH-PAI), states that it is the official organization for TT.[13] It establishes minimum standards for education and training for TT practitioners and teachers. Their Board recognizes individuals who demonstrate expertise and competency in TT and adhere to the Standards and Scope of Practice and the Ethics of TTIA as well as State/Province or national licensure or regulatory requirements. However, the TTIA is not accredited by an accrediting body or state approval agency recognized by the US DOE.

TT courses may be also offered to the general public through community education, healing clinics, and holistic schools. Non-licensed health care professionals may practice TT within their families, religious or spiritual community and among friends.

[10]Source: http://yogaalliance.org// accessed March 29, 2011.
[11]Source: http://www.therapeutic-touch.org accessed August 10, 2010.
[12]Source: http://www.quackwatch.org/01QuackeryRelatedTopics/tt2.html , accessed December 21, 2010.
[13]Source: http://www.therapeutic-touch.org , accessed December 20, 2010.

State laws vary regarding the regulation of TT. In many states, TT is considered an extension of health care skills, so most health care professionals who practice TT are covered under their existing professional state licensure requirements. Many hospitals have established policies allowing nurses and other staff to perform TT on patients at no extra charge. Hospital-based TT programs are subject to continuous quality improvement (CQI) activities required by The Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Healing touch[14]

Healing Touch (HT) is an energy therapy that uses gentle hands-on touch or hands slightly above to assists in balancing health and well-being. The balancing technique focuses on seven main chakras and joints of the extremities where the energy field is believed to be stagnant or not moving properly. HT is used in a wide variety of settings including hospitals, long term care facilities, private practices, hospices, and spas.

Janet Mentgen, RN, developed the HT Certificate Program in 1989 as a continuing education program for nurses, massage therapists, other health care professionals, and lay persons. At that time certification was provided through the American Holistic Nurses Association.

In 1996, Healing Touch International (HTI) was created to certify HT practitioners and instructors, coordinate HT research, assist integration of HT into healthcare settings, and promote HT around the world in accordance within an established Code of Ethics, Standards of Practice and Scope of Practice. There are five levels to the certification process that apply didactic and experiential learning modalities. Once completed, the individual is credentialed as a Certified Healing Touch Practitioner (CHTP) or Instructor (CHTI).

The Healing Touch International Certificate Program is:

1. Endorsed by the California Board of Nursing;
2. Approved by the American Holistic Nurses Association, which is an accredited organization of the American Nurses Credentialing Center's Commission on Accreditation;
3. Approved by the National Certification Board for Therapeutic Massage & Bodywork (NCBTMB), which is an accredited organization of the National Commission for Certifying Agencies (NCCA).

However, neither of the accrediting organizations is recognized by the US DOE.

Craniosacral therapy[15]

Craniosacral therapy (CST) is a manual, holistic approach to healing originated by osteopath William G. Sutherland in the early twentieth century. Today, one of the most ardent promoters is osteopath John Upledger through his organization, the Upledger Institute. CST practitioners believe that the craniosacral system has its own physiologic rhythms and frequency. CST uses gentle touch and pressure to correct imbalances in the body's subtle rhythms of the craniosacral system that can lead to disease and disorders of the body and mind.

CST practitioners include licensed chiropractors, osteopaths, massage therapists, physical therapists and naturopaths, and unlicensed practitioners. Training in CST may be offered through an accredited healthcare practitioner program or institutions for CST. In the US, the International Alliance of Healthcare Educators and the Upledger Institute offer training and

[14]Source: http://www.healingtouchinternational.org/ accessed December 21, 2010.
[15]Source: http://www.craniosacraltherapy.org/Whatis.htm, accessed December 21, 2010.

certification in CST.[16] The Biodynamic Craniosacral Therapy Association of North America (BCTA/NA) offers Registered Craniosacral Therapist status to those who have received certification in CST and are members in good standing.[17] However, none of these organizations is accredited by an accrediting agency or state approval agency recognized by the US DOE.[18]

Meridian-based techniques

Meridian-based techniques are energy healing practices in which acupuncture points (acupoints) found along the body's energy meridian are stimulated to correct disturbances in energy flow that are believed to underlie physical or emotional illness, including thoughts. While acupuncture is the most well-known, other techniques have been developed that integrate acupoint stimulation with a variety of Western medical practices. Integrated treatment approaches are growing in popularity notably among Veterans.

***Acupuncture*[19]**

Acupuncture is a healing practice within traditional Chinese medicine (TCM) and one of the oldest in the world. The popularity of acupuncture in the US has grown since the early 1970s among consumers as well as traditional allopathic medicine practitioners.

In TCM, the body is believed to be balanced by two opposing but complementary forces: yin and yang. Yin represents cold, slow, or passive aspects of the person, while yang represents hot, excited, or active aspects. Consequently, disease is caused by an imbalance in yin and yang leading to a blockage in the flow of qi. Acupuncture is used to restore and maintain health by stimulating specific points on the body that correspond to the blockage in qi.

Acupuncture uses a variety of techniques, but one of the most common involves penetrating the skin with thin, metallic needles that can be stimulated manually or electrically. The U.S. Food and Drug Administration (FDA) established manufacturing and labeling standards for needles used in acupuncture: that is, needles must be sterile, nontoxic, and labeled for single use by qualified practitioners only.

Most states require a license to practice acupuncture, but their requirements for education and training standards vary. The US DOE recognizes the Accreditation Commission for Acupuncture and Oriental Medicine as an accreditation body for professional master's level programs in acupuncture and oriental medicine.

VATAP addressed the literature on acupuncture in a separate report (Adams 2007), and an update of that report is currently underway.
Therefore, acupuncture will not be addressed in this report.

Other meridian-based energy practices

While these practices are not used exclusively in psychotherapy, there is growing interest in acupoint stimulation to improve the effectiveness of exposure therapies in persons with stress and anxiety disorders. Also called "energy psychology" or "emotional acupressure", it involves

[16] Source: http://www.uiahe.com/ accessed August 11, 2010.
[17] http://www.craniosacraltherapy.org/CSTA_home.html accessed August 11, 2010.
[18] U.S. Department of Education's Office of Postsecondary Education Database of Accredited Programs and Institutions [http://ope.ed.gov/accreditation/], searched August 11, 2010.
[19] source: http://nccam.nih.gov/health/acupuncture/introduction.htm , accessed December 21, 2010.

using sequences of finger taps called “algorithms” on "acupuncture points" while the patient focuses on a problem. Examples are Thought Field Therapy® (TFT® or the Callahan Techniques®[20]; the Tapas Acupressure Technique® (TAT®)[21] and Gary Craig’s Emotional Freedom Techniques (EFT™)[22]. Practitioners of these techniques claim they have achieved results much more safely, quickly and less traumatically than established techniques, particularly in treating PTSD (L. Garland: personal communication April 4, 2011).

Typically, training in these techniques is safe, portable and simple. It is offered to professionals in energy healing and alternative medicine as well as traditional healthcare practitioners; however, a formal background in healthcare is not necessarily required. For-profit and not-for-profit sources offer multimedia didactic and experiential training opportunities through books, videos, workshops, training centers and on-line sessions. In VA, training in universal protocols for TAT® or EFT™ would likely be targeted toward licensed practitioners such as nurses, social workers and psychologists.

Acceptance of meridian-based energy healing techniques varies across and within health professions. For example, the American Psychological Association does not endorse continuing education in TFT® (APA Monitor, 1999a) despite growing pressure to do so. And while each proprietary technique has its own training and educational requirements, there is recognition among energy practitioners that standards for training and certification and rigorous research of effectiveness must be established (L. Garland: personal communication April 4, 2011). To that end, the Association for Comprehensive Energy Psychology has developed research guidance and training and certification standards in EFT™.[23] It is difficult to track the certification status of every technique, but a sampling of their websites did not provide information on accreditation by an accreditation body recognized by the US DOE.

Regulatory requirements for these techniques vary from state to state; they may be considered an extension of health care skills covered under existing professional state licensure requirements or banned outright (APA Monitor, 1999b).

METHODS

TAP conducted extensive searches of the published research literature and applied inclusion criteria as a filter for selecting the best evidence from published research that address the questions in this review. The included studies were critically appraised by applying scientific rules of evidence to help interpret the persuasiveness of the evidence for linking cause to effect based primarily on the type and quality of the research design. Ultimately, the conclusions should follow logically from the evidence appraised in the review, and the recommendations for policy should be linked to the strength (or quality) of the evidence.

TAP approached this review by first focusing on available systematic reviews, then updating these systematic reviews with newer, relevant primary studies that would meet their inclusion criteria.

Systematic reviews

[20]Source: http://www.rogercallahan.com/ accessed March 28, 2011.
[21]Source: http://www.tatlife.com/ accessed March 29, 2011.
[22] Source: http://www.eftuniverse.com/ accessed March 29, 2011.
[23]Source: http://www.energypsych.org/displaycommon.cfm?an=1&subarticlenbr=225, accessed April 4, 2011.

A systematic review applies explicit, reproducible methods that emphasize study quality and minimize potential bias in addressing a focused question, usually about a particular intervention (Mulrow, 1997). In contrast, a traditional narrative review frequently addresses a broad topic and fails to report objectives or identify articles and methods for critical appraisal. Additionally, they may be susceptible to bias in the selection, analysis, and synthesis of studies, and may ignore methodological weaknesses in primary studies, leading to erroneous conclusions. For this reason, narrative reviews were not included in this report.

Systematic reviews can be quantitative (e.g. meta-analytic) where primary studies permit, or qualitative. Systematic review production requires a minimum threshold level of available primary research tailored to the review question. Therefore, presence or absence of published systematic reviews provides an immediate signal of the general status of a body of research literature.

Search strategies

Initial multiple comprehensive searches were carried out from March through August 2010 on the following databases: MEDLINE, EMBASE, and CurrentContents via Dialog Information Services. Multiple terms were used for an array of energy therapies (see Appendix 1). A second round of searches was carried out in December 2010. In each search, VATAP applied an evidence search filter for retrieving RCTs, Clinical Studies, meta-analyses, systematic reviews, and guidelines (see Appendix 2).

Results were limited to human studies and articles published in English. Hand searching of the end references of retrieved articles was performed by the author (Adams).

Inclusion criteria

- Adults subjects;
- Intervention of interest is classified as an biofield energy practice;
- Systematic reviews and HTAs with an adequate description of objectives, quality assessment and analysis, and interpretable results;
- Primary studies (randomized controlled trials (RCT) only):
  - o Experimental group comprised N≥ 12 subjects with the disease or disorder of interest (studies of only healthy subjects will be excluded);
  - o Comparator group consisted of sham, control, usual care or no intervention (studies comparing one CAM intervention to another will be excluded if there is no sham intervention included);
  - o Only validated outcome measures were used (studies attempting to validate outcome measures will be excluded);
  - o Able to calculate the effects of energy therapy (studies of multisensory interventions that do not stratify analyses sufficiently to discern independent treatment effects will be excluded).

Grading the evidence

VATAP applied to each included study the U.S. Preventive Services Task Force (USPSTF) classification for grading the strength of policy recommendations based on the quality of the evidence. This framework is designed to ensure that the critical appraisal process and final product are *"methodologically sound, scientifically defensible, reproducible, and well documented."*[24] The framework includes:

[24]U.S. Preventive Services Task Force Procedure Manual. Agency for Healthcare Research and Quality (AHRQ). AHRQ Publication No. 08-05118-EF. July 2008. www.ahrq.gov.

- Classifying individual studies according to a revised hierarchy of research design;
- Assessing internal validity of individual studies and assigning to one of three categories—"good," "fair," and "poor";
- Assessing external validity and applicability;
- Assessing both the certainty of the evidence about, and the magnitude of, the net benefits of an intervention;
- Assigning a recommendation grade for that intervention.

A detailed description of the USPSTF framework is available at www.ahrq.gov. A modified summary is presented in Appendix 3. One author (Adams) reviewed the search results, applied inclusion criteria, abstracted and graded each article included in this report.

RESULTS

Electronic searches and hand searches of end references of retrieved articles produced a total of 635 citations. After review of title and abstract information, 147 articles were retrieved as potentially relevant to the review: 107 articles were excluded from review (see Table 3 in References). 36 articles met inclusion criteria (See Table 1):

- 20 qualitative systematic reviews and meta-analyses:
  - 9 Cochrane reviews;
  - 1 Cochrane protocol;
  - 10 other peer reviewed systematic reviews;
- 16 RCTs.

Details of each systematic review and RCT were abstracted in Appendix 4 Tables 3 and 4, respectively. The prevailing research is of contact or non-contact TT or reiki for alleviation of pain symptoms and TT for modifying behaviors associated with dementia, depression, stress and anxiety disorders.

Interest in meditative movements such as Qigong, Tai Chi and Yoga is growing as potential alternatives for improving a number of health conditions, particularly in the elderly. However, aside from the studies identified in this review, existing research has approached the evaluation of these practices as holistic forms of exercise. While few would argue against their value as forms of low-impact exercise, the intent of this review is to focus on interventions for treating specific medical conditions with emphasis on the use of a healer.

The internal validity of the systematic reviews was high and received the highest USPSTF designation of "good". This should not be construed as a reflection of the quality of the individual studies in the review, but rather the quality of the systematic review process. In fact, all systematic reviews stressed the overall poor quality of the available evidence for determining the effectiveness of any energy therapy for any health condition. The additional evidence from RCTs found in this report confirms these findings.

For assessment of external validity, all evidence included in this report would appear to be based on study populations that could be generalized to the Veteran population. Eleven systematic reviews (So 2008; Astin 2000) and two primary studies (Abbott 2001; Pippa 2007) received the highest USPSTF rating of "good", indicating adequate generalizability of the results

to the Veteran population. All other reviews received lower or unclear (?) grades due to the poor validity or reporting of individual trial results that made generalizability of the findings to the Veteran population difficult to determine.

Regarding the ability to determine the net benefit of energy therapies on health outcomes, one systematic review (So 2008) and three primary studies (Astin 2006; Assefi 2008; and Walach 2008) received "moderate" ratings based on the extent and quality of the available evidence. All others received "low" ratings.

The majority of systematic reviews and primary studies received a USPSTF recommendation grade of "I" indicating that the level of certainty in the current evidence is insufficient, i.e. lacking, of poor quality or conflicting, to assess the net benefit of energy therapies. So (2008) found that there was moderate level of certainty in the evidence that TT and Reiki showed a small, positive analgesic effect on acute and chronic pain, thereby receiving "C" grades, whereas the evidence for HT conferred less certainty in the conclusions and warranted an "I" grade.

Evidence from the highest quality primary studies (Abbott 2001; Astin 2006; Walach 2008; Assefi 2008) that offered the greatest degree of certainty in the results received a "D" recommendation against using the interventions in managing pain, as the energy therapies in these studies showed no net benefit on pain.

The existing evidence was limited by failure to adhere to methodological and reporting standards to which health researchers in allopathic medicine must adhere. Among the most common flaws were:

- Inadequate sample sizes usually not based on power calculations;
- Insufficient description of the randomization method;
- Insufficient description of the placebo control;
- Heterogeneous comparison groups;
- Failure to control for placebo effects;
- Inadequate blinding of assessor or subject to allocation;
- Inadequate description of the intervention with respect to type, frequency and duration of treatment;
- Variation in the intervention;
- Inadequate use of relevant or valid outcome measures;
- Variable experience of practitioners.

Table 1. Summary of Available Evidence of the Effectiveness of Energy Therapy with USPSTF Quality Assessment

	Intervention	Findings	USPSTF Quality Assessment			
			Internal Validity	External Validity	Certainty	Recommendation Grade
Dementia						
Hansen (2006) Cochrane review	Massage, therapeutic touch (TT) (Only TT included here)	• Limited evidence from one RCT of the addition of TT to verbal encouragement to eat for the normalization of nutritional intake, with no severe side effects. • Overall data are insufficient to draw general conclusions about benefits of TT in dementia. • Many limitations: lacking detailed description of randomization procedure, concealed allocation, intervention, and effect parameters	Good	Fair	Low	I
Woods (2009) Primary study	Contact TT	• Improvement in restlessness at one of five time periods compared to controls • Results of contact TT were similar to placebo • Many limitations: underpowered, antidepressant medications not controlled for, heterogeneous salivary cortisol measurements, different version of TT used	Fair	Fair	Low	I
Hawranik (2008) Primary study To reduce agitation in persons with Alzheimer's Disease	TT Simulated TT Usual Care	• TT may decrease the frequency of physically nonaggressive behaviors more so than simulated TT or usual care • Neither the reason for this effect nor the ability to sustain an effect over time was clear. • Limitations: Underpowered, inconsistent data collection	Fair	Fair	Low	I
Schizophrenia						
Gorcznski (2010) Cochrane review	Yoga	• Exercise programs with yoga are feasible in people with schizophrenia and may produce positive physical and mental health effects and improved well being. • Limitations: based on one small trial, high risk of bias	Good	Fair	Low	I
Depression/Stress/ Anxiety disorders						
Kessler (2002) Primary study	Thought Field Therapy (TFT)	• In perpetrators of domestic violence with PTSD, the results do not support the use of TFT as an effective component of therapy in reducing anxious arousal, intrusive experiences, or defensive avoidance, which are common symptoms of PTSD. • Multiple study design limitations with high risk of bias, ITT analysis lacking	Poor	Poor	Low	I
Wells (2003) Primary study	Emotional Freedom Technique (EFT)	• In persons with phobias of small animals, preliminary evidence suggests that EFT may have a significant effect on avoidance behavior that lasts 6-9 months in persons with at least moderate phobia severity • Multiple study design limitations—some addressed, but ITT analysis lacking	Poor	Fair/Poor	Low	I
Joyce (2007) Cochrane protocol	Reiki	In progress-results pending	-	-	-	-
Robinson (2007) Cochrane review	TT	No evidence met inclusion criteria	Good	?	Low	I
Dowd (2007) Primary study	HT, coaching, combined, wait list control	• In college students seeking help with stress, HT mind clearing had better immediate results on stress and comfort vs. other interventions or waitlist controls, but coaching had better carryover results on both outcomes. • Multiple study design limitations	Poor	Fair	Low	I
Da Silva (2009) Systematic review	Yoga	• 3 small case series suggest improvement in depression and PTSD symptoms using yoga as either monotherapy or augmentation to medication for PTSD, but requires confirmation with RCTs. • Inconclusive due to low methodological quality	Poor	Fair	Low	I

	Intervention	Findings	USPSTF Quality Assessment			
			Internal Validity	External Validity	Certainty	Recommendation Grade
Wang (2009) Systematic review	Tai Chi (TC)	• For psychosocial well-being TC may improve depression and anxiety, but needs further study • Inconclusive due to overall low methodological quality, poor reporting, heterogeneity in design, and conflicting results	Good	Fair	Low	I
Korn (2009) Primary study	Polarity therapy (PT)	• Significant reduction in stress, depression, bodily pain, vitality and general health compared to enhanced respite control among Native American caregivers of Alzheimer's Disease patients. • PT is feasible and culturally acceptable in this population.	Good	Poor	Low	I
Wound healing						
O'Mathúna (2007) Cochrane review	TT	Inconclusive evidence for use of TT to heal acute or chronic wounds	Good	Poor	Low	I
Pain						
Aghabati (2010) Primary study Cancer pain	TT, placebo, control	• Results suggest that TT was more effective in decreasing pain and fatigue of cancer patients undergoing chemotherapy than the usual care group • There was a decreasing trend in pain and fatigue scores in the placebo group compared with the usual care group, indicating a possible placebo effect • Limitations: investigator not blinded to treatment allocation, all female, investigator=practitioner	Poor	?	Low	I
McCormack (2009) Primary study Post-surgical pain	TT, sham, control	• Modest analgesic effect on post-surgical pain in elderly versus sham or control, but no effect on mood or relaxation. • Limitations: choice of outcome measures, pain med consumption not measured, inexperienced TT practitioner	Poor	Poor	Low	I
So Pui (2008) Cochrane review	Healing touch (HT), TT, or Reiki	• Overall data are limited by heterogeneity • TT and Reiki=modest analgesic effect on acute and chronic pain versus sham or no treatment. • HT= inconclusive evidence • Impact of practitioner experience or type of TT is unclear.	Good	Good	Moderate	TT or Reiki=C HT =I
Assefi (2008) Primary study	TT, Reiki	• Neither Reiki nor TT improved symptoms of fibromyalgia. • Rigorous studies are needed.	Good	Fair	Moderate	D
Nourbakhsh (2008) Primary study Lateral epicondylitis	Oscillating-Energy Manual Therapy (OEMT)	• Data suggest clinically and statistically significant improvements in grip strength, pain intensity, function, and activity tolerance in subjects with chronic LE after OEMT treatment compared with placebo. • Limitations: small sample size, significant loss to follow up, outcome measurement, confounders, unclear mechanism of action	Poor	?	Low	I
Han (2004) Cochrane review Rheumatoid arthritis	TC	• N=4 CCTs with 206 participants • A potential benefit of TC on lower extremity range of motion and self-reported frequency and enjoyment of exercise but the dose (frequency, intensity and duration) of TC required is unclear. • Evidence of effect of TC on patient-reported pain or QoL unclear. • Low quality trials, underpowered with heterogeneity	Good	Fair	Low	I
O'Connor (2003) Cochrane review Carpal tunnel syndrome	Yoga	• One small trial (n=51) with high risk of bias of an 8-week yoga program produced short-term improvement in pain relief and Phalen's sign compared to wrist splinting • No significant difference between yoga vs. splinting on nocturnal waking, Tinel's sign, grip strength or peripheral nerve conduction • Research needed to compare treatments and determine duration of benefit.	Good	Fair	Low	I

	Intervention	Findings	USPSTF Quality Assessment			
			Internal Validity	External Validity	Certainty	Recommendation Grade
Abbott (2001) Primary study	Distant healing (DH), face to face healing, placebo, no healing	• A specific effect of face-to-face or distant healing on chronic musculoskeletal pain could not be demonstrated over eight treatment sessions in this study population. • Subjects in healing groups in both parts I and II reported significantly more `unusual experiences' during the sessions, eg. body jerking, twitching, seeing colors or lights and sensing something from the healer, but the clinical relevance of this is unclear.	Good	Good	High	D
Cardiovascular conditions						
Lee (2010) Systematic review Lowering resting blood pressure in the eldery	TC	• Benefits of TC versus other forms of physical exercise are unclear. • Moderate quality of studies but insufficient number of trials or total sample size, concurrent use of medications and heterogeneity of intervention limit findings.	Good	Fair	Low	I
MacIntyre (2008) Primary study TT in coronary artery bypass recovery	HT	• Significant decreases in anxiety scores and in length of stay (LOS) among all HT subjects compared to the other groups • Significant reduction in outpatient LOS among HT subjects • No decrease in use of pain med or anti-emetic meds or incidence of atrial fibrillation	Poor	Poor	Low	I
Pippa (2007) Primary study Chronic atrial fibrillation	Qigong	• In patients with chronic AF and preserved ventricular function had significant improvement in functional capacity who used Qigong compared to baseline • Well tolerated and liked • Low methodological quality	Poor	Good	Low	I
Lee (2007) Systematic review Hypertension	Qigong	• Qigong added to antihypertensives lowered systolic blood pressure (SBP) significantly more than antihypertensives alone or vs. waiting list. • No differences in SBP noted between Qigong as a sole treatment vs. exercise, or in combination with conventional therapy vs. muscle relaxation + conventional therapy • Low methodological quality of included studies	Good	?	Low	I
Other						
Logghe (2010) Systematic review Fall prevention, fear of falling and balance	TC	• Inconclusive evidence of effectiveness in preventing falls, decreasing fear of falling or improving balance in healthy people over age 50 years. • Potentially positive dose–effect relationship • Role of patient characteristics (e.g. living setting, activity level), intervention dose and effect maintenance) on the measured outcomes should be clarified	Good	Fair	Low	I
vanderVaart (2009) Systematic review Multiple conditions	Reiki	• Inconclusive evidence of effectiveness due to serious methodological and reporting limitations	Good	?	Low	I
Lee (2009) Systematic review Type 2 diabetes	Qigong	• Insufficient evidence of effectiveness due to serious methodological and reporting limitations	Good	?	Low	I
Lee (2008) Systematic review Osteoporosis	TC	• Insufficient evidence of effectiveness for TC in preventing or treating osteoporosis due to serious methodological and reporting limitations	Good	Fair	Low	I

	Intervention	Findings	USPSTF Quality Assessment			
			Internal Validity	External Validity	Certainty	Recommendation Grade
Walach (2008) Primary study Chronic Fatigue Syndrome	Laying-on of hand Healing prayer Healing meditation Reiki Chakra therapy	• Distant healing has no statistically significant effect on mental or physical health • Expectation of improvement did improve outcome	Good	Fair	Moderate	D
Elder (2007) Primary study Weight loss maintenance	Qigong Tapas Acupressure Technique® (TAT) Self-directed support (SDS)	• Feasibility study suggests more weight loss was maintained with TAT than with SDS or Qigong after 24 weeks in obese adults from a group model HMO • Results limited by inadequate statistical analysis and trial design; RCT ongoing	Poor	Good	Low	I
Astin (2006) Primary study HIV	DH/prayer	• No significant treatment effects of DH observed in HIV patients on antiretroviral therapy • Overall good methodological quality but underpowered due to large amounts of missing data	Good	?	Moderate	D
Taylor-Piliae (2004) Systematic review Improving aerobic activity	TC	• N= 7 trials (2 RCTs, 2 quasi-experimental studies, 3 cross-sectional) • The degree of improvement in aerobic capacity depends on the exercise intensity, duration, and frequency, as well as the subject's initial level of physical activity. Gender may also play a role. • Generally low quality trials, underpowered with heterogeneity	Fair	Fair	Low	I
Ernst (2003) Update of Astin (2000) Systematic review Mixed conditions	DH	• 8 non-randomized studies • 9 RCTs: 8 prospective (6 with no effect of healing, 2 with positive effects but with significant methodological limitations); 1 retrospective • Potential adverse effects reported: vasoconstriction, relapse among schizophrenics • Inconclusive evidence	Fair	Fair	Low	I
Ramaratnam (2002) Cochrane review Epilepsy	Yoga	• Conflicting results from 2 studies with high risk of bias • Inconclusive results for use of yoga as an add-on to antiepileptic drugs	Good	Fair	Low	I
Green (1999) Systematic review All conditions	Craniosacral therapy (CST)	• A causal relationship between restrictions/ misalignments in the movement of cranial bones and health has not been shown • Assessment of craniosacral dysfunction by CST practitioners is unreliable • The effectiveness of CST has not been demonstrated in well-designed research protocols	Good	?	Low	I

CONCLUSIONS/DISCUSSION

The available evidence of the effectiveness of energy therapies represented in this review to heal a wide range of health conditions is, at best, inconclusive. The most promising use of energy therapies appears to be for alleviating acute and chronic pain, where TT and Reiki may show a modest analgesic effect based on self-reported outcomes rather than consumption of pain medicine, but results from other clinical trials could not confirm these findings.

The effectiveness of putative energy therapies is further obscured by the inability of energy therapy practitioners to demonstrate the existence of universal energy forces that form the basis of their healing practices. In the absence of a sound scientific rationale, researchers and practitioners must rely on measuring the effects of energy interventions on health outcomes using valid and accepted methods of clinical trial design that reduce bias and maximize the certainty of the results. The most rigorous studies in this review (Assefi 2008; Abbott 2001) failed to demonstrate any specific effect of energy therapies on healing pain beyond a placebo effect.

Of all the energy therapies represented in allopathic medicine, perhaps TT and to a lesser extent HT have received the most attention among health professionals based on decades of strong advocacy among key professional leaders, particularly in nursing. However, an increasing number of researchers have challenged the validity of the early effectiveness research, on which proponents of TT based their claims, as inadequate, flawed and misleading (O'Mathúna 2000). Recent high quality research identified in this report does not support claims of effectiveness with any certainty. Therefore, TT has attained a level of professional legitimacy that is, at best, premature.

Likewise, meridian-based energy interventions such as EFT™, TAT® and TFT® are growing in popularity as integrative therapeutic options for a wide range of health conditions. Of particular interest to VA is providing effective care to Veterans with PTSD; to that end mindfulness-based interventions that incorporate meridian-based energy therapies have attracted much attention. While some VA practitioners in trauma care have reported anecdotal success, these techniques have not been adequately researched to help identify optimal candidacy and context for the intervention, which are needed to determine its cost-effectiveness.

Critiques of the CAM literature in this review and in others note recurring themes of significant bias in the design of primary studies and of publication bias in many CAM resources favoring positive results (Junhua 2007; Manheimer 2009). All health interventions must apply accepted rules of science to demonstrate evidence of effectiveness. In evidence-based healthcare, the principle of “do no harm” applies to all healthcare systems and philosophies; therefore, interventions labeled as CAM or integrative must be assessed by the same set of rules. It is the burden of the proponents of energy-based therapies to back up their claims with valid and reproducible results, rather than relying on the results from poor research and unreliable claims.

Therefore, the TAP concludes that the current evidence is insufficient to assess the net health benefit of energy therapies. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined. If offered, Veterans should understand the uncertainty about the balance of benefits and harms.

A word about placebos and their effects

Medical interventions are administered within a context. This context may include environment, belief systems of the individual or practitioner, savvy marketing and testimonials. These contextual factors are believed to produce either a positive (placebo) effect or a negative (nocebo) effect. I say "believed", because the very existence of a placebo effect has been the subject of scientific controversy for several decades. Since the mid-twentieth century, its existence has been purported to be based on what is now viewed as flawed research. A recent Cochrane systematic review did not find that placebo interventions have important clinical effects; although there may be some influence on patient-reported outcomes, especially in pain and nausea, biased reporting and study design prevented drawing firm conclusions (Hróbjartsson 2010).

Broadly defined, a placebo is an inert intervention that mimics the treatment intervention under study. The ideal placebo should be both biologically inert ***and*** psychologically credible, i.e. the patient believes it will work and cannot distinguish it from the treatment being studied.

Clinical trial methodology attempts to identify and measure the effects of contextual factors by use of placebo and no-treatment groups to which subjects are randomized. In the absence of adequate control groups, it is not possible to discern an intervention's healing effects from the body's natural recuperative capacity or other factors. This methodology assumes a causal relationship between the contextual effects and the outcome of interest, as well as the independent effects of placebo and treatment, but it is not without its critics.

New research into the psychological, neurobiological and methodological aspects of placebo effects is challenging both the interpretation of this causal relationship and the validity of current methods used to estimate the magnitude of these effects. These aspects include: the role of expectancy; a complex and little understood interplay among contextual factors; the interplay between contextual factors and the treatment intervention; bias in trial design; and communication between patient and clinician (Bausell 2002; Hróbjartsson 2010).

The studies in this review attempted to account for contextual factors using traditional clinical trial methodology such as randomization and placebo controls. Whether the desired effect from energy healers is due to the manipulation of universal energy forces or some other mix of contextual factors cannot be determined from the existing research.

Greater understanding of the role of placebos in producing changes in health outcomes would assist clinicians and researchers in determining the net benefits and harms of all therapeutic interventions. Scarce resources might be better directed at carrying out research on these other non-specific factors that can enlighten a holistic, evidence-based approach to patient-centered care regardless of the intervention. As Caspi (2002) so eloquently states:

> *"Understanding how placebos produce change is the key to evidence-based human therapy. Therefore, whether one believes that the placebo effect is a myth or not, it is imperative that more conceptual work and further research be conducted to make the implicit explicit (i.e. specifying the remaining "unspecified" elements of human therapy) and to examine the underlying conditions and predicting models that would results in more reliable effects of "specific," "non-specific," and preliminary constituents of all forms of therapy on human health and well-being."*

To that end, Hróbjartsson (2010) identified important areas in which to focus future placebo research:

- The impact of bias (such as response bias and bias due to co-intervention) on the estimated effect of placebos;
- The association between type of outcome and bias;
- Factors in the clinical setting that are associated with different placebo effects, and;
- The duration of placebo effects.

ONGOING RESEARCH

In July 2010 and again in April 2011, TAP searched the database at www.clinicaltrials.gov for ongoing and completed research into the efficacy or effectiveness of any energy therapy in healthcare. Seventeen active studies, 20 completed studies, and one not-yet open study were found (see Table 2). NCCAM was the lead sponsor of 10 completed studies, of which TAP was only able to locate published results for three. Of these three, two were included in this report (Assefi 2008; Korn 2009); the other (Kutner 2008) addressed massage therapy which was excluded as a non-energy therapy (see Table 3).

The Soul Medicine Institute, a nonprofit dedicated to promoting and researching the fields of Energy Medicine and Energy Psychology, has sponsored 11 studies: of the four completed studies, results for one (Church 2009) have been published, but this was excluded from review due low sample size (see Table 3).

Most completed studies have had sufficient time to post results either on public registration databases such as www.clinicaltrials.gov or publish them in the peer reviewed literature. All sponsors should encourage investigators to publish their results regardless of the findings. This would minimize publication bias and allow assessors, clinicians and policy makers to make a more valid and reliable evaluation of these interventions.

Table 2. Ongoing and completed clinical trials of energy therapies from www.clinicaltrials.gov

Note: Searched on July 15, 2010 and April 12, 2011 using the following terms for energy interventions: therapeutic touch OR reiki OR touch therapy OR healing touch OR energy therapy OR applied energy OR biofield therapy OR energy healing OR smoothing OR centering OR unruffling OR laying on of hands OR polarity therapy OR "quantum touch" OR "emotional freedom technique" OR "non touch therapy" OR "distant healing" OR "healing prayer" OR "healing meditation" OR "chakra therapy" OR "chakra healing" OR centering OR unruffling OR "meridian tapping" OR "simple touch" OR "mindfulness" | Adult | Phase I II III IV

NCT Identifier	Sponsor	Title	Phase	Status	Completion date	Results/ Comments
NCT00981396	Soul Medicine Inst	The Effect of **EFT** in Smokers Failing a Smoking Cessation Program	?	Active	September 2012	Non-randomized, double blind
NCT01117545	Soul Medicine Inst	Psychological Symptom Change in Veterans After Six Sessions of **EFT**: A RCT	III	Active	June 2013	Wait-list controlled
NCT00737399	Soul Medicine Inst	Anxiety and Depression Levels in Cancer Patients After Self-Application of **EFT**	?	Active	December 2012	Uncontrolled
NCT01250431	Soul Medicine Inst	Gene Expression Correlates of PTSD Symptom Change After **EFT**: A RCT	?	Active	November 2012	Wait-list controlled
NCT01327690	Soul Medicine Inst	Mental Health in Veterans and Families After Group Therapies (CBT, **EFT**, waitlist)	?	Active	December 2013	Randomized, single blind
NCT00526266	Soul Medicine Inst	Evaluating Physiological Markers of Emotional Trauma: A Randomized Controlled Comparison of Mind-Body Therapies (**EFT**, DB, none)	?	Active	June 2012	Randomized, double blind

NCT Identifier	Sponsor	Title	Phase	Status	Completion date	Results/ Comments
NCT00788502	Stanford U.	Stress Reduction During In Vitro Fertilization	?	Active	Dec 2011	Uncontrolled
NCT00565305	Univ. of Iowa	**Healing Touch** Breast Cancer Study	II?	Active	March 2008	Randomized, single blind
NCT00641394	Soul Medicine Inst	Effect of Psychotherapy on Stress Biochemistry: A RCT of Psychotherapy and **EFT**	?	Active, not recruiting	September 2010	Randomized, double blind
NCT00065208	NCCAM; the Cleveland Clinic	**Reiki/Energy Healing in Prostate Cancer**	I/II	Active, not recruiting	Dec 2009	Randomized, double blind
NCT00288795	Univ. of Rochester	A Randomized Study of **Polarity** or Massage **Therapy** to Reduce Fatigue in Breast Cancer Patients During Radiation **Therapy**	I/II	Active, not recruiting	Jan 2010	Randomized
NCT00632398	NCI	Multimedia Program About Massage Therapy for Cancer Patients and Their Care Partners	II	Active, not recruiting	Not reported	Randomized
NCT00574145	NCI	Examining the Effect of **Healing Touch** on Radiotherapy-induced Fatigue		Active, not recruiting	NR	Randomized
NCT00617500	Sociedade Hospital Samaritano	Climacteric Clinical Trial : the Use of Complementary Therapy and Hormonal Replacement	IV	Active, not recruiting	Dec 2008	Randomized
NCT00967395	Frederiksberg University Hospital	Effect of **Healing** on Rheumatoid Arthritis (RA healing)	?	Active, not recruiting	Jan 2009	Randomized, double blind
NCT00526565	Kaiser-Permanente	Randomized Trial of **Tapas Acupressure** for Weight Loss Maintenance (LIFE)	II III	Active, not recruiting	Feb 2011	Randomized, single blind
NCT00533663	Stanford U.	**Healing Touch** During Chemotherapy Infusions for Women With Breast Cancer	?	Active, recruiting	NR	Uncontrolled
NCT00743041	Soul Medicine Inst	The Effect of **EFT** on Psychological States in a Veterans Population: A RCT	?	Completed	May 2010	
NCT01117532	Soul Medicine Inst	Brief Group Intervention Using **EFT** for Depression in College Students: A RCT	?	Completed	May 2010	
NCT00514956	Soul Medicine Inst	Effect of **EFT** and Diaphragmatic Breathing on PTSD	I	Completed	January 2009	Church (2009) N=7 excluded
NCT00668993	Soul Medicine Inst	**EFT** Versus a Waitlist for Food Cravings: A RCT	?	Completed	February 2009	
NCT00010751	NCCAM	Effects of **Reiki** on Painful Neuropathy and Cardiovascular Risk Factors	II	Completed	June 2004	
NCT00032721	NCCAM	The Use of **Reiki** for Patients With Advanced AIDS	II	Completed	Sept 2003	
NCT00051428	NCCAM	**Efficacy of Reiki in the Treatment of Fibromyalgia**	I	Completed	Feb 2005	Assefi 2008
NCT00065195	NCCAM	REST: Reducing End-of-Life Symptoms With **Touch**	II	Completed	March 2007	Kutner 2008
NCT00079521	NCCAM	The Effect of **Therapeutic Touch** on Bone Formation in Postmenopausal Women After Wrist Fracture	II	Completed	April 2006	
NCT00084123	NCCAM	**Healing Touch** in Advanced Cervical Cancer Patients: Immune Effects and Mechanisms	II	Completed	April 2007	
NCT00100035	NCCAM	**Polarity Therapy for American Indian Caregivers of Dementia Patients**	I	Completed	April 2007	Korn 2009
NCT00440089	Univ. of Calif, San Diego	Effects of **Hands**-on-**Healing** vs. **Touch** for Fatigue and Inflammation in Breast Cancer Survivors	II/III	Completed	Sept 2009	
NCT00612443	Univ. of Wisconsin, Milwaukee	**Healing Touch** and Health-Related Quality of Life in Women With Breast Cancer in Women With Breast Cancer Receiving Radiation Therapy	II/III	Completed	Dec 2008	
NCT00321880	NCI	**Healing Touch** in Treating Patients Receiving Chemotherapy for Acute Myeloid Leukemia or Acute Lymphocytic Leukemia	?	Completed	NR	
NCT00533780	Stanford U.	Effect of **Healing Touch** on the Experience of Women Undergoing	?	Completed	August 2008	

NCT Identifier	Sponsor	Title	Phase	Status	Completion date	Results/ Comments
		Treatment for Breast Cancer				
NCT00293293	Masonic Cancer Center, Univ. of Minnesota	Hypnosis, Massage Therapy, and **Healing Touch** in Treating Patients Receiving Chemotherapy for Ovarian Epithelial Cancer or Peritoneal Cavity Cancer	?	Completed	January 2010	
NCT00759512	University of Toledo Health Science Campus	Effects of **Therapeutic Touch** on Osteoarthritis of the Knee	?	Completed	Aug 2005	
NCT00029783	NCCAM	Efficacy of **Distant Healing** in Glioblastoma Treatment	II	Completed	June 2005	
NCT00067717	NCCAM	**Distance Healing** in Wound Healing	I/II	Completed	May 2008	
NCT00079534	NCCAM	**Distant Healing** for HIV/AIDS	NR	Completed	Dec 2003	
NCT01057056	Tel-Aviv Sourasky Medical Center	The Role of **Mind Body** Therapy in Geriatric Rehabilitation	I/II	Not yet open		

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Excluded studies

Table 3. Studies excluded from review and reason for exclusion

Citation	Reason for exclusion
(2005)	opinion
Abbot (2001)	in Ernst 2003
Allaire (2002)	editorial
Astin (2000)	multiple applications, superseded by newer Cochrane reviews
Bardia (2006)	superseded by So (2008)
Barrett (2002)	editorial
Blankfield (2001)	in So 2008
Bowden (2010)	healthy subjects only
Brønfort, G. (2004)	not energy therapy
Cao, H. (2010)	cupping not evaluated separately
Chung Jenny (2002)	Multisensory, not evaluated separately
Cook Cynthia (2004)	in So 2008
Cox, T. (2003)	editorial
Crawford (2006)	insufficient reporting of methods
Darby (2002)	Inadequate controls
Davidson, P. (2003)	not SR
Davies, E. (2000)	not research
Davies, E. (2001)	not research
Denison, B. (2004)	in So 2008
DiNucci Ellen, M. (2005)	not SR or RCT
Engers, A. (2008)	CAM not focus of review
Ernst, E. (2003)	Editorial
Ernst, E. (2009)	Editorial
Fazzino, D. L. (2010)	not SR, all references covered in other reviews
Feinstein, D. (2010)	not SR or RCT
Forbes (2008)	Not CAM
Frank (2003)	covered in So 2008
Frank (2007)	covered in So 2008
Fulda, K. G. (2007)	Abstract only
Gerard, S. (2003)	Spiritual healing
Gillespie, L. D. (2009)	superseded by Logghe 2010
Golomb, B. A. (2010)	not energy
Gorski, T. (2002)	editorial
Green, S. (2002)	editorial
Group (2005)	Not SR or RCT
Hagemaster, J. (2000)	poorly reported N=?
Harkness, E. F. (2000)	in Astin 2000
Henkelman, W. J. (2004)	opinion
Hermans, D. (2007)	not energy therapy
Howe, T. E. (2007)	yoga not eval'd separately
Hulse (2010)	N < 10
Jahnke (2010)	no quality assessment
Jain (2010)	missing methods
Jonas (2003)	no data
Kelly (2004)	Effectiveness not focus of study
Kerr (2007)	not RCT
Krucoff (2005)	in other interventions
Kutner (2008)	Not energy
Larden (2004)	reviewed by Robinson 2007
Leduc (2001)	infants
Lee (2008)	superseded by vanderVaart 2009
Lee (2010)	not energy
Lewis (2006)	not energy therapy
Liu (2010)	superseded by Logghe 2010, no quality score application
London (2002)	editorial
Lusby (2003)	opinion
Mackay (2004)	healthy subjects only

Citation	Reason for exclusion
Mannen (2002)	editorial
Maville (2008)	healthy subjects
McCarthy (2006)	not CAM
McElligott (2003)	in Robinson 2007
McElroy-Cox (2009)	not SR
Mehl-Madrona (2007)	missing outcome information, unintelligible
Monroe Carolyn (2009)	superseded by So 2008
Morone (2007)	superseded by other reviews, quality assessment not applied to results
O'Mathuna (2009)	Abstract only
Patterson (2008)	not energy therapy
Peters (1999)	superseded by recent Cochrane reviews
Pohl (2007)	in Jain 2010
Post-White (2003)	in So 2008
Randi (2002)	editorial
Raviv (2009)	not RCT
Reece (2005)	no comparator
Reid (2008)	no quality assessment, outcomes details insufficient
Rindfleisch (2010)	Not SR or RCT
Robinson (2006)	superseded by 2007 review
Rogers (2009)	not SR, no quality assessment
Roggla (2003)	opinion
Rosa (1998)	< 2000
Rosa (2002)	editorial
Rowe (2005)	Inadequate controls
Sampson (2002)	editorial
Schwartz (2004)	Not effectiveness study
Shiflett (2002)	reviewed by vanderVaart 2009
Shore (2004)	multiple diagnoses, self-diagnoses
Sloan (2005)	editorial
Smith (2002)	superseded by So 2008
Smith (2003)	in So 2008
Targ (1997)	not SR or RCT
Targ (2002)	Not SR or RCT
Taylor (2001)	effects of HT not measured
Tsang (2008)	superseded by da Silva 2009 and Rogers 2009
Tsang (2007)	superseded by So 2008
Tsubono (2009)	N<10
Vitzthum (2009)	not a SR
Wang (2006)	N<10
Wardell (2006)	N<10
Wardell (2004)	not SR, newer reviews available
Wayne (2007)	superseded by Lee 2008, additional data are of lower quality
Wiesendanger, H. (2001)	in Ernst (2003)
Wilkinson Dawn, S. (2002)	superseded by So 2008
Winstead-Fry, P. (2002)	opinion
Winstead-Fry, P. (2002)	editorial
Winstead-Fry, P. (1999)	no full text
Woods Diana, L. (2005)	superseded by Woods 2009
Woods Diana, L. (2002)	in Hawranik 2008
Xin, L. (2007)	no formal quality assessment

APPENDIX 1. SEARCH STRATEGIES

Searches were carried out over several months on Dialog databases: MEDLINE, EMBASE, Current CONTENTS, AMED, and PsychINFO as well as PubMed, The Cochrane Library and the HTA Database. Concepts and their synonyms included the broad and specific variations on a wide range of energy and touch therapies.

Searches for the broad and specific concepts related to energy therapies and:

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Name:     TOUCHTHERAPY
----- ---------
   1. S (TOUCH(N)THERAP? OR NON()TOUCH?)/TI(N)(THERAP? OR TREAT? OR
     HEAL?)/TI
   2. S ENERG?(N)(TREAT? OR THERAPY OR THERAPIES OR THERAPEUT? OR HEAL?)
   3. S (NONTOUCH OR NON()TOUCH)/TI (N)(TREAT? OR THERAPY OR THERAPIES OR
     THERAPEUT? OR HEAL?)/TI
   4. S TOUCH?(1N)(TREAT? OR THERAPY OR THERAPIES OR THERAPEUT? OR
     HEAL?)/TI
   5. S (CENTERED? OR CENTERING OR UNRUFFL? OR TRANSFER?)/TI(N)(ENERGY OR
     ENERGY()FIELD? ?)/TI
   6. S REIKI?/TI,DE,GS
   7. S (EMOTIONAL(N)FREEDOM OR EMOTIONAL(N)FREEDOM(N)TECHNIQUE? OR EFT)/TI
   8. S BIOFIELD()THERAP?/TI,AB,DE OR POLARITY(N)THERAP?/TI OR TAT/TI OR
     MERIDIAN(N)TAPPING/TI
   9. S DISTANT(N)HEAL?/TI OR SPIRITUAL?(N)HEAL?/TI
  10. S LAYING(2W)HANDS/TI OR HEALING(W)PRAYER?/TI OR
     HEAL?(N)MEDITATION?/TI OR CHAKRA(N)THERAP?/TI OR CHAKRA(N)HEAL?/TI
  11. S S HEALING()TRADITION?/TI
  12. S LAYING(N)HAND?/TI AND (ALTERNATIVE OR CAM OR COMPLEMENTARY OR
     TRADITION? OR HEAL?)/TI,DE,GS
  13. S LAYING(2N)HAND?/TI AND (ALTERNATIVE OR CAM OR COMPLEMENTARY OR
     TRADITION? OR HEAL?)/TI,DE,GS
  14. S HEALING()TRADITION?/TI
  15. S S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S12 OR
     S13 OR S14

Name:     TOUCHEVIDENCE
----- ---------
   1. S (TOUCH(N)THERAP? OR NON()TOUCH?)/TI(N)(THERAP? OR TREAT? OR
     HEAL?)/TI
   2. S ENERG?(W)(TREAT? OR THERAPY OR THERAPIES OR THERAPEUT? OR HEAL?)/TI
   3. S (NONTOUCH OR NON()TOUCH)/TI (W)(TREAT? OR THERAPY OR THERAPIES OR
     THERAPEUT? OR HEAL?)/TI
   4. S TOUCH?(N)(TREAT? OR THERAPY OR THERAPIES OR THERAPEUT? OR HEAL?)/TI
   5. S (CENTERED? OR CENTERING OR UNRUFFL?)/TI(N)(ENERGY OR ENERGY()FIELD? ?)/TI
   6. S REIKI?/TI,DE,GS
   7. S (EMOTIONAL(N)FREEDOM OR EMOTIONAL(N)FREEDOM(N)TECHNIQUE? OR EFT)/TI
   8. S BIOFIELD()THERAP?/TI,AB,DE OR POLARITY(N)THERAP?/TI OR MERIDIAN(N)TAPPING/TI
   9. S DISTANT(N)HEAL?/TI OR SPIRITUAL?(N)HEAL?/TI
  10. S LAYING(2W)HANDS/TI OR HEALING(N)PRAYER?/TI OR HEAL?(N)MEDITATION?/TI OR
        CHAKRA(N)THERAP?/TI OR CHAKRA(N)HEAL?/TI
  11. S HEALING()TRADITION?/TI
  12. S LAYING(N)HAND?/TI AND (ALTERNATIVE OR CAM OR COMPLEMENTARY OR
     TRADITION? OR INTEGRATIVE? OR HEAL?)/TI,DE,GS
  13. S LAYING(2N)HAND?/TI AND (ALTERNATIVE OR CAM OR COMPLEMENTARY OR
     TRADITION? OR HEAL?)/TI,DE,GS
  14. S HEALING()TRADITION?/TI
  15. S S15 AND PY=2000:2010
  16. S DOUBLE()BLIND? OR RANDOM()ALLOCAT? OR RANDOM?()CONTROL?
  17. S CONTROL?()CLINICAL()(TRIAL? OR STUDY OR STUDIES)
  18. S SINGLE()BLIND()METHOD? OR DOUBLE()BLIND()METHOD?
```

```
  19. S (DOUBLE()DUMMY OR MASK OR SHAM OR PLACEBO) AND CONTROL?()(TRIAL? OR
      STUDY OR STUDIES)
  20. S CLINICAL()TRIAL? ? OR CLINICAL TRIALS!
  21. S PLACEBO/DE
  22. S PLACEBO/TI,AB
  23. S RANDOM?/TI,AB,DE,DT
  24. S RESEARCH DESIGN/DE
  25. S DT=RANDOM?
  26. S META()ANALY? OR META-ANALY? OR METAANALY? OR DT=META-ANALYSIS
  27. S COCHRANE () (REVIEW? OR REPORT? OR COLLABOR? OR GROUP?)
  28. S GUIDELINE? OR CONSENSUS()DEVELOPMENT()CONFER? OR
      RECOMMENDATION?/TI,DE OR PROTOCOL? OR CLINICAL()PATH? OR
      POSITION()PAPER? OR CRITICAL()PATH?
  29. S (METHOD? OR COMPREHEN? OR TECHNOLOG? OR CRITICAL? OR EVIDENCE? OR
      SYSTEM?)(2N)(REVIEW? OR REPORT? OR APPRAISAL? OR ASSESS?) OR DT=REVIEW
      OR  TECHNOLOGY()ASSESSMENT()BIOMEDICAL/DE


Name:     TOUCHEVIDENCEUPDATE
----- ---------
   1. S (TOUCH(N)THERAP? OR NON()TOUCH?)/TI(N)(THERAP? OR TREAT? OR
      HEAL?)/TI
   2. S ENERG?(N)(TREAT? OR THERAPY OR THERAPIES OR THERAPEUT? OR HEAL?)/TI
   3. S (NONTOUCH OR NON()TOUCH)/TI (N)(TREAT? OR THERAPY OR THERAPIES OR
      THERAPEUT? OR HEAL?)/TI
   4. S TOUCH?(N)(TREAT? OR THERAPY OR THERAPIES OR THERAPEUT? OR HEAL?)/TI
   5. S (CENTERED? OR CENTERING OR UNRUFFL?)/TI(N)(ENERGY OR ENERGY()FIELD? ?)/TI
   6. S REIKI?/TI,DE,GS
   7. S (EMOTIONAL(N)FREEDOM OR EMOTIONAL(N)FREEDOM(N)TECHNIQUE? OR EFT)/TI
   8. S BIOFIELD()THERAP?/TI,AB,DE OR POLARITY(N)THERAP?/TI OR MERIDIAN(N)TAPPING/TI
   9. S DISTANT(N)HEAL?/TI OR SPIRITUAL?(N)HEAL?/TI
  10. S LAYING(2W)HANDS/TI OR HEALING(N)PRAYER?/TI OR
      HEAL?(N)MEDITATION?/TI OR CHAKRA(N)THERAP?/TI OR CHAKRA(N)HEAL?/TI
  11. S (HEALING()TRADITION? OR LAYING(N)HAND? OR SIMPLE(W)TOUCH OR
      SMOOTHING OR UNRUFFLING OR QUANTUM OR SIMPLE TOUCH?)/TI AND
      (ALTERNATIVE OR CAM OR COMPLEMENTARY OR TRADITION? OR INTEGRATIVE? OR
      HEAL?)/TI,DE,GS
  12. S LAYING(2N)HAND?/TI AND (ALTERNATIVE OR CAM OR COMPLEMENTARY OR
      TRADITION? OR HEAL?)/TI,DE,GS
  13. S S11/TI
  14. DELETE S13
  15. S (HEALING()TRADITION? OR LAYING(N)HAND? OR SMOOTHING OR UNRUFFLING
      OR QUANTUM OR SIMPLE TOUCH?)/TI AND (ALTERNATIVE OR CAM OR
      COMPLEMENTARY OR TRADITION? OR INTEGRATIVE? OR HEAL?)/TI,DE,GS
  17. S DOUBLE()BLIND? OR RANDOM()ALLOCAT? OR RANDOM?()CONTROL?
  18. S CONTROL?()CLINICAL()(TRIAL? OR STUDY OR STUDIES)
  19. S SINGLE()BLIND()METHOD? OR DOUBLE()BLIND()METHOD?
  20. S (DOUBLE()DUMMY OR MASK OR SHAM OR PLACEBO) AND CONTROL?()(TRIAL? OR
      STUDY OR STUDIES)
  21. S CLINICAL()TRIAL? ? OR CLINICAL TRIALS!
  22. S PLACEBO/DE
  23. S PLACEBO/TI,AB
  24. S RANDOM?/TI,AB,DE,DT
  25. S RESEARCH DESIGN/DE
  26. S DT=RANDOM?
  27. S META()ANALY? OR META-ANALY? OR METAANALY? OR DT=META-ANALYSIS
  28. S COCHRANE () (REVIEW? OR REPORT? OR COLLABOR? OR GROUP?)
  29. S GUIDELINE? OR CONSENSUS()DEVELOPMENT()CONFER? OR
      RECOMMENDATION?/TI,DE OR PROTOCOL? OR CLINICAL()PATH? OR
      POSITION()PAPER? OR CRITICAL()PATH?
  30. S (METHOD? OR COMPREHEN? OR TECHNOLOG? OR CRITICAL? OR EVIDENCE? OR
      SYSTEM?)(2N)(REVIEW? OR REPORT? OR APPRAISAL? OR ASSESS?) OR DT=REVIEW
      OR  TECHNOLOGY()ASSESSMENT()BIOMEDICAL/DE
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Name:     TOUCHAMEDUPDATE
----- ---------
   1. S QI()GONG OR JI()GONG OR TAI()CHI OR TAJ()CHI
   2. S QIGONG OR JIGONG OR TAICHI OR TAJCHI
   3. S ENERGY()THERAP?
   4. S REIKI
   5. S EMOTIONAL()FREEDOM
   6. S MERIDIAN()TAPPING?
   7. S POLARITY()THERAP?
   8. S SMOOTHING/TI
   9. S SMOOTHING
  10. S QUANTUM()TOUCH
  11. S SIMPLE()TOUCH
  12. S UNRUFFLING
  13. S HANDS()ON
  14. S HANDS()ON/TI
  15. S HANDS()ON(N)HEAL?
  16. S CRANIOSACRAL()THERAP?
  17. S CUPPING/TI
  18. S CRYSTAL?()THERAP?/TI
  19. S CRYSTAL?()THERAP?
  20. S FAITH()HEAL?
  21. S HEAL?()TOUCH?
  22. S THERAPEUT?()TOUCH?
  23. S THERAPEUT?()TOUCH?/TI
  24. S MAGNET?()THERAP?
  25. S MEDITATION?/TI
  26. S MOXIBUSTION
  27. S SMOXIBUSTION/TI
  28. DELETE S27
  29. S MOXIBUSTION/TI
  30. S REFLEXOLOG?/TI
  31. S YOGA/TI
  32. S MASSAGE()THERAP?
  33. S MASSAGE()THERAP?/TI
  34. S BIOFIELD()THERAP?
  35. S BIOFIELD
  36. S BIOELECTROMAGNETIC(1N)THERAP?
  37. S BIOELECTROMAGNET?
  38. S DISTAN?(N)HEAL?
  39. S HEAL?(N)INTENTION?
  40. S MINDFULLNESS
  41. S MINDFULNESS
  42. S LAY?(1N)HAND?
  43. S LAYING()ON(1N)HANDS
  44. S POLARITY()THERAP?
  45. S APPLIED()ENERG?
  46. S APPLIED()ENERGY/TI
  47. S ENERGY()HEAL?
  48. S S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S9 OR S10 OR S11 OR S12
      OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S23 OR S24
      OR S25 OR S27 OR S28 OR S29 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36
      OR S37 OR S39 OR S40 OR S41 OR S42 OR S43 OR S45
  49. S DOUBLE()BLIND? OR RANDOM()ALLOCAT? OR RANDOM?()CONTROL?
  50. S CONTROL?()CLINICAL()(TRIAL? OR STUDY OR STUDIES)
  51. S SINGLE()BLIND()METHOD? OR DOUBLE()BLIND()METHOD?
  52. S (DOUBLE()DUMMY OR MASK OR SHAM OR PLACEBO) AND CONTROL?()(TRIAL? OR
      STUDY OR STUDIES)
  53. S CLINICAL()TRIAL? ? OR CLINICAL TRIALS!
  54. S PLACEBO/DE
  55. S PLACEBO/TI,AB
```

```
56. S RANDOM?/TI,AB,DE,DT
57. S RESEARCH DESIGN/DE
58. S DT=RANDOM?
59. S META()ANALY? OR META-ANALY? OR METAANALY? OR DT=META-ANALYSIS
60. S META()ANALY? OR META-ANALY? OR METAANALY? OR DT=META-ANALYSIS
61. S UTILITY?/TI OR ACCURAC?/TI,DE OR ACCURAT?/TI OR SENSITIVITY/TI,DE
   OR SPECIFICITY/TI,DE OR SPECIFIC/TI OR UTILIZATION?/TI,DE
62. S SCREEN?/TI,DE OR SURVEILL?/TI,DE
63. S COCHRANE () (REVIEW? OR REPORT? OR COLLABOR? OR GROUP?)
64. S GUIDELINE? OR CONSENSUS()DEVELOPMENT()CONFER? OR
   RECOMMENDATION?/TI,DE OR PROTOCOL? OR CLINICAL()PATH? OR
   POSITION()PAPER? OR CRITICAL()PATH?
65. S (METHOD? OR COMPREHEN? OR TECHNOLOG? OR CRITICAL? OR EVIDENCE? OR
   SYSTEM?)(2N)(REVIEW? OR REPORT? OR APPRAISAL? OR ASSESS?) OR DT=REVIEW
   OR  TECHNOLOGY()ASSESSMENT()BIOMEDICAL/DE
66. S ANIMAL? ?/DE, GS NOT HUMAN? ?/DE, GS
67. S S46 AND (S47 OR S49 OR S50 OR S51 OR S54 OR S56)
68. S S46 AND (S57 OR S61)
69. S S46 AND S62
70. S S46 AND S63
71. SS S46 AND (S57/TI OR S61/TI OR S62/TI OR S63/TI)
```

APPENDIX 2. EVIDENCE FILTER USED IN DIALOG SEARCHES

```
Name:  Lengthy Evidence Filter: RCTs/CTs/Meta analyses/ Cochranes/Guidelines
 /Systematic Reviews
EVIDENCETWO
----- ---------
   1. S DOUBLE()BLIND? OR RANDOM()ALLOCAT? OR RANDOM?()CONTROL?
   2. S CONTROL?()CLINICAL()(TRIAL? OR STUDY OR STUDIES)
   3. S SINGLE()BLIND()METHOD? OR DOUBLE()BLIND()METHOD?
   4. S (DOUBLE()DUMMY OR MASK OR SHAM OR PLACEBO) AND CONTROL?()(TRIAL? OR
     STUDY OR STUDIES)
   5. S CLINICAL()TRIAL? ? OR CLINICAL TRIALS!
   6. S PLACEBO/DE
   7. S PLACEBO/TI,AB
   8. S RANDOM?/TI,AB,DE,DT
   9. S RESEARCH DESIGN/DE
  10. S DT=RANDOM?
  11. S META()ANALY? OR META-ANALY? OR METAANALY? OR DT=META-ANALYSIS
  12. OR METAANALY?
  13. S UTILITY?/TI OR ACCURAC?/TI,DE OR ACCURAT?/TI OR SENSITIVITY/TI,DE
  14. OR SPECIFICITY/TI,DE OR SPECIFIC/TI OR UTILIZATION?/TI,DE
  15. S SCREEN?/TI,DE OR SURVEILL?/TI,DE
  16. S COCHRANE(n)(REVIEW? OR REPORT? OR COLLABOR? OR GROUP?)
  17. S GUIDELINE? OR CONSENSUS()DEVELOPMENT()CONFER? OR
     RECOMMENDATION?/TI,DE OR PROTOCOL? OR CLINICAL()PATH? OR
     POSITION()PAPER? OR CRITICAL()PATH?
  18. S (METHOD? OR COMPREHEN? OR TECHNOLOG? OR CRITICAL? OR EVIDENCE? OR
     SYSTEM?)(2N)(REVIEW? OR REPORT? OR APPRAISAL? OR ASSESS?) OR DT=REVIEW
     OR  TECHNOLOGY()ASSESSMENT()BIOMEDICAL/DE
  19. S ANIMAL? ?/DE, GS NOT HUMAN? ?/DE, GS
```

APPENDIX 3. SUMMARY OF US PREVENTIVE SERVICES TASK FORCE PROCEDURE MANUAL: MODIFIED FOR THIS SYSTEMATIC REVIEW

1. A. Classify individual studies according to a hierarchy of research design.

I:	Properly powered and conducted RCT; well-conducted systematic review or meta-analysis of homogeneous RCTs
II-1:	Well-designed controlled trial without randomization
II-2:	Well-designed cohort or case-control analytic study
II-3:	Multiple time series with or without the intervention; dramatic results from uncontrolled experiments
III:	Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees

B. Criteria for incorporating systematic reviews in USPSTF reviews

Relevance to one or more of the study questions for this review: Did the review include the desired study designs and relevant population(s), settings, exposure/interventions, comparator(s), and outcome(s)?
Comprehensiveness of sources considered/search strategy used
Validity of the conclusions
Recency: Is the review recent enough not to require bridging searches?

2. A. Assess internal validity of individual studies and assigning to one of three categories—"good," "fair," and "poor"

Good	Meets all internal validity criteria: comparable groups are assembled initially and maintained throughout the study (follow up at least 80%); reliable and valid measurement instruments are used and applied equally to the groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention to confounders in analysis. For RCTs, intention to treat analysis is used.
Fair	If any or all of the following problems occur, without fatal flaws noted in the "poor" category below: generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention to treat analysis is done for RCTs.
Poor	If any of the following fatal flaws exists: groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied at all equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. For RCTs, intention to treat analysis is lacking.

B. Assess the internal validity of systematic reviews and assigning to one of three categories—"good," "fair," and "poor"

Good	Recent, relevant review with comprehensive sources and search strategies; explicit and relevant selection criteria; standard appraisal of included studies; and valid conclusions.
Fair	Recent, relevant review that is not clearly biased but lacks comprehensive sources and search strategies
Poor	Outdated, irrelevant, or biased review without systematic search for studies, explicit selection criteria, or standard appraisal of studies

3. Global rating of external validity

Good	The study differs minimally from the Veteran population, and only in ways that are unlikely to affect the outcome; it is highly probable (>90%) that the clinical experience with the intervention observed in the study will be attained in the Veteran setting.
Fair	The study differs from the Veteran population in a few ways that have the potential to affect the outcome in a clinically important way; it is only moderately probably (50%-89%) that the clinical experience with the intervention in the study will be attained in the Veteran setting.
Poor	The study differs from the Veteran population in many ways that have a high likelihood of affecting the clinical outcomes; the probability is low (<50%) that the clinical experience with the intervention observed in the study will be attained in the Veteran setting.

4. Levels of certainty regarding net benefit

Level of certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative Veteran populations. These studies assess the effects of the intervention on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the intervention on health outcomes, but confidence in the estimate is constrained by factors such as: o the number, size, or quality of individual studies o inconsistency of findings across individual studies o limited generalizability of findings to the Veteran population, or o lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of; o the limited number or size of studies o important flaws in study design or methods o inconsistency of findings across individual studies o gaps in the chain of evidence o findings not generalizable to routine VA care, or o a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

5. Putting it all together: Assigning a recommendation grade for that intervention

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	**Moderate**	**Small**	**Zero/Negative**
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient (I)			

6. Defining USPSTF grades and suggestions for practice

Grade	Grade definitions The USPSTF…	Suggestions for Practice
A	…recommends the intervention. There is high certainty that the net benefit is substantial.	Offer/provide this intervention.
B	…recommends the intervention. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial	Offer/provide this intervention.
C	…recommends against routinely providing the intervention. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this intervention only if there are other considerations in support of offering/providing the intervention in an individual patient.
D	…recommends against the intervention. There is moderate or high certainty that the intervention has no net benefit or that the harms outweigh the benefits.	Discourage the use of this intervention.
I statement	…concludes that the current evidence is insufficient to assess the net benefit of the intervention. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	If offered, patients should understand the uncertainty about the balance of benefits and h arms.

APPENDIX 4. EVIDENCE INCLUDED IN THIS REVIEW

Table 4. Systematic reviews and meta-analyses of energy therapies

Citation/Objective(s)	Design	Outcome Measures	Findings
Green (1999) Craniosacral therapy (CST) for any condition	Searches of MEDLINE, EMBASE, Healthstar, Mantis, Allied and Alternative Medicine, Scisearch and Biosis through February 1999, gray literature and end references of retrieved articles **Inclusion criteria:** • Primary data on CST for effectiveness • Primary data on technical or physiologic aspects of CST-interrater reliability and pathophysiology **Quality assessment referenced but not detailed** **Qualitative synthesis**	• Pathophysiological mechanisms linking craniosacral dysfunction to health outcomes • Inter-rater reliability of assessment of craniosacral dysfunction • Effectiveness of CST on health outcomes	• A causal relationship between restrictions/misalignments in the movement of cranial bones and health has not been shown • Assessment of craniosacral dysfunction by CST practitioners is unreliable • The effectiveness of CST has not been demonstrated in well-designed research protocols
Ramaratnam (2002) (up to date as of Nov 2009) Cochrane review Yoga for epilepsy	Searches of the Cochrane Epilepsy Group Specialized Register (10 November 2009), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 4, 2009), MEDLINE (Ovid, 1950 to week 5, October 2009), registries of the Yoga Biomedical Trust and Research Council for Complementary Medicine, extensive array of in and out of India contacted for completed (unpublished or published) or ongoing studies. Search terms and strategies detailed. **Inclusion criteria:** • RCTs and CCTs • Any type of epilepsy • Any language, age group or gender. **Types of interventions:** Any classical Indian yoga **Comparators:** any **Quality assessment:** not explicitly stated, but authors used Cochrane Reviewer's Handbook guidelines **Analysis:** qualitative and meta-analysis	• Seizure frequency • Seizure duration • Drop out rates due to noncompliance or other reasons • Reduction in dosage of anticonvulsants (yes/no) • Improvement in QoL (if assessed by standardized, reliable and valid instruments)	N=2 unblinded studies enrolling a total of 50 subjects (18 treated with yoga, 32 to control interventions). Antiepileptic drugs were continued in all. Quasi-randomization in one study. **Results study #1** **Seizure free for 6 months:** • Yoga vs. sham yoga OR 14.54 (95% CI 0.67 to 316.69) • Yoga vs. no treatment group OR 17.31 (95% CI 0.80 to 373.45) **Reduction in seizure frequency** • Yoga vs. sham yoga group - WMD -2.10 (95% CI -3.15 to -1.05) • Yoga vs. no treatment group – WMD -1.10 (95% CI -1.80 to -0.40) **> 50% reduction in seizure frequency** • Yoga vs. sham yoga group OR 81.00 (95% CI 4.36 to 1504.46) • Yoga vs. no treatment group OR 158.33 (95% CI 5.78 to 4335.63) **> 50% reduction in seizure duration** • Yoga vs. sham yoga group OR 45.00 (95% CI 2.01 to 1006.75) • Yoga vs. no treatment group OR 53.57 (95% CI 2.42 to 1187.26). **Results study #2** • No significant difference between the yoga vs. Acceptance and Commitment Therapy (ACT) groups in seizure free rates, 50%or greater reduction in seizure frequency or seizure duration at 1 year follow-up. • Yoga group showed significant improvement in the Satisfaction With Life Scale (SWLS) • ACT group had significant improvement in the WHOQOL-BREF scale (over time). **Authors' conclusions:** *"No reliable conclusions can be drawn regarding the efficacy of yoga as a treatment for epilepsy."* **Authors' recommendations:** Further studies are needed that address the deficiencies in existing research and important ethical considerations. Yoga should be evaluated as an add-on to antiepileptic drugs and not as a sole intervention.
Ernst (2003) Update of Astin (2000) (distant healing, spiritual	Searches of MEDLINE, EMBASE, and Cochrane Library databases from 2000 – 2002, authors' own files and experts in the field.	• Multiple outcomes	• 8 non-randomized studies • 9 RCTs: 8 prospective (6 showed no effect of healing, 2 showed positive effects but with significant methodological limitations); 1 retrospective • Potential adverse effects reported: vasoconstriction, relapse among schizophrenics

Citation/Objective(s)	Design	Outcome Measures	Findings
healing, mental healing, faith healing, prayer, TT, Reiki, distant healing, psychic healing, and external qigong).	**Inclusion criteria:** • All clinical studies (including non-randomized trials) • Human subjects • All languages **Quality assessment** process not detailed; each included study assessed in narrative form **Qualitative synthesis**		**Authors' recommendations:** *"Future trials testing the efficacy of any form of distant healing should adhere to rigorous trial designs which are adequately suited to the research question that is being asked. Such trials should preferably be randomised, control for placebo effects, have sample sizes based on proper power calculations, use validated primary outcome measures and include a full description of the actual interventions that are being tested."* **Authors' conclusions:** *"…the evidence that any method of distant healing is associated with specific effects has been decisively weakened through the recent publication of several rigorous and trustworthy clinical trials. In the final analysis, however, the question of whether distant healing is more than a placebo remains unanswered…"*
O'Mathúna (2003) Cochrane review Non-contact TT on healing of acute wounds	Searches carried out in November 2007 using the following databases: Cochrane Wounds Group Specialised Register, The Cochrane Central Register of Controlled Trials (CENTRAL) - The Cochrane Library 2007 Issue 4, 2007 Ovid MEDLINE, EMBASE and CINAHL through November 2007. **Inclusion criteria:** • All randomized or quasi-randomized controlled trials (RCT) • Compared with a placebo, another treatment, or no treatment control • TT used as a stand-alone or adjunctive treatment **Quality assessment detailed**	• Any quantifiable means of measuring wound healing rates or degrees of healing, eg. changes in area, volume, depth or circumference of the wound, or time to heal.	N= 4 trials **Overall results:** • Insufficient evidence for the effectiveness of TT for healing acute wounds. Pooled data using a random effects model showed no statistically significant difference in complete healing (RR 1.03, 95% CI 0.12 to 8.60) • Evidence is conflicting and of poor quality • All trials used patients undergoing a biopsy from healthy skin and the findings may not be generalizable to other wound types. • **Authors' conclusions:** *"Further research into the effects of TT on acute wound healing is unlikely to be a good use of resources."*
O'Connor (2003) Cochrane review Non-surgical, non-steroidal treatments for carpal tunnel syndrome (yoga only reported)	Searches of the Cochrane Neuromuscular Disease Group specialized register (searched March 2002), MEDLINE (January 1966 to February 7 2001), EMBASE (January 1980 to March 2002), CINAHL (January 1983 to December 2001), AMED (searched 1984 to January 2002), Current Contents (January 1993 to March 2002), PEDro and reference lists of retrieved articles. **Inclusion criteria:** • Randomized or quasi-randomized studies • Any language • Subjects diagnosed with carpal tunnel syndrome who had not previously undergone surgical release. • All non-surgical and nonsteroidal injection treatments. **Quality assessment** based on Cochrane Reviewer's Handbook **Qualitative synthesis**	Primary: improvement in clinical symptoms after at least 3 months post treatment. Secondary outcome measures at least 3 months post treatment included: • improvement in : o functional status and/or HRQoL; o objective physical examination measures, such as grip, pinch strength, and sensory perception; o neurophysiological parameters; • clinical improvement at < 3 months of follow-up; • clinical improvement at 1 year post treatment; • need for surgical release of the flexor retinaculum during follow-up	N= 1 trial with 51 subjects (data on 42 reported) employed or retired individuals from a geriatric center and an industrial site in 1994-1995 with carpal tunnel syndrome, median age, 52 years; range, 24-77 years. High risk of bias. **Overall results:** • No significant effect in favour of yoga was demonstrated for improving nocturnal waking, Tinel's sign or grip strength after eight weeks of treatment. • A significant effect of yoga on improving pain WMD -1.40 (95% CI -2.73 to -0.07) on a 0 to 10 point VAS and Phalen's sign RR 5.25 (95% CI 1.28 to 21.47) after 8 weeks of treatment. **Authors' conclusions:** *"In summary, there is limited evidence that yoga results in superior short-term pain relief and improved outcome for Phalen's sign compared to wrist splinting. There is limited evidence that yoga and wrist splinting provide similar short-term improvement in nocturnal waking, Tinel's sign and grip strength."* **Authors' Recommendations:** *"More trials are needed to compare treatments and ascertain the duration of benefit."*
Han (2004) Cochrane review (updated through 2010)	Searches of MEDLINE (1966 to September 2002), CINAHL databases (1982 to September 2002), Cochrane Controlled Trials	• Number of tender joints per patient • Number of swollen joints per patient • Pain	N=4 CCTs with 206 participants included of low study quality = 0-1 out of 5 point scale **Overall results** • No clinically important or statistically significant effect of TC on most outcomes of disease

Citation/Objective(s)	Design	Outcome Measures	Findings
TC for rheumatoid arthritis	Registry and databases of the Beijing Chinese Academy of Traditional Medicine and the Chinese Biomedical Database up to December 2003, manual searching of reference lists of selected trials. Search strategy detailed. No language restrictions. **Inclusion criteria:** • RCTs or CCTs • Controls were no therapy, sham or other active therapy. • Ambulatory adults with a diagnosis of RA • Trials of exercise programs with TC instruction or incorporating principles of TC philosophy **Quality assessment** using Jadad 5 point scale **Meta-analysis**	• Physician global assessment • Patient global assessment • Functional status • Acute phase reactants • Radiological damage • Safety • Withdrawals overall • Additional Outcomes • Range of motion • Grip strength	activity, including ADLs, tender and swollen joints and patient global overall rating. • Statistically significant improvement in ankle plantar flexion (WMD: 24.00 degrees, 95% CI, 3.34, 44.66) and lower extremity flexion (WMD: 34.00 degrees, 95% CI, 10.79, 57.21) (N=1 trial) • No adverse effects found • Consistent and statistically greater withdrawals from the control group (RR 0.37, 95%CI: 0.19, 0.72) than the TC group; 11 withdrawals out of 101 (11%) in the TC group and 25 out of 88 (28%) among controls. • A statistically significant improvement in enjoyment of exercise/rest (p=.0002) and self-reported benefit from exercise/rest (p=.006) at end of therapy (10 weeks) and 4 months later (N=1 trial) **Authors' conclusions:** *"The results suggest Tai Chi does not exacerbate symptoms of rheumatoid arthritis. In addition, Tai Chi has statistically significant benefits on lower extremity range of motion."* **Authors' research recommendations:** *"A study comparing Tai Chi to another form of exercise that includes patient reported quality of life and pain is recommended. Also, when designing future studies it is important to consider the quality of the measurement and reporting of the dose (frequency, intensity and duration) of Tai Chi received by participants."*
Taylor-Piliae (2004) TC for improving aerobic activity	Searches of 7 databases (PubMed, CINAHL, Current Contents, Cochrane Library, Digital Dissertations, PsychINFO, and SocAbstracts) with multiple search terms used. Search date not reported. Other literature sources not reported. **Inclusion criteria** • All languages • Primary comparative studies • Outcome measure = aerobic capacity • Quality score > 21 **Quality assessment** using Chan and Bartlett quality scoring tool, range 0-32 **Meta-analysis**	Aerobic capacity effect size (ES)	N= 7 trials with 344 subjects included (2 RCTs, 2 quasi-experimental studies, 3 cross-sectional) • Mean quality scores= 25.1, range 22 to 28 (SD - 2.0);only 1 study used blinded group assignment • Group sample sizes ranged from 7 to 27 older adults [average age men=55.7 years (SD = 12.7); women 60.7 years (SD = 6.2)] including those with heart disease. • Styles of TC used were classical Yang style (N=4 trials), modified movement style (N=1 trial), or unspecified (N=2 trials) • Sessions ranged from 45 to 60 minutes, 3 to 5 times per week, from 12 to 52 weeks. • Dropout rates in a 52-week intervention = 26.5%, in the 12-week intervention= 17% and 16-week intervention=8%. **Overall results (ES_{sm} = standardized mean difference effect size)** • In cross-sectional studies, ES_{sm} =1.01; CI = +0.37, +1.66 • In the experimental studies, ES_{sm}=0.33; CI = -0,41, +1.07 (NS) • Aerobic capacity in women (ES_{sm} = 0.83; CI = -0.43, +2,09) > in men (ES_{sm} = 0.65; CI = -0.04, +1.34), though not statistically significant. • Aerobic capacity > in subjects performing classical Yang style TC (ES_{sm} = 1.10; CI = +0.82, +1.38), and with a 52-week TC exercise intervention (ES_{sm} = 0.94; CI = +0.06, +1.81) vs. sedentary subjects (ES_{sm} = 0.80; CI = +0.19, +1.41) • The degree of improvement in aerobic capacity depends on the exercise intensity, duration, and frequency, as well as the subject's initial level of physical activity. **Authors' conclusions:** *"This meta-analysis suggests that Tai Chi may be an additional form of aerobic exercise. The greatest benefit was seen from the classical Yang style of Tai Chi exercise when performed for 1-year by sedentary adults with an initial low level of physical activity habits… Given the limited number of studies pertaining to the effects of Tai Chi exercise on aerobic capacity in women (n - 126), these results need to be interpreted with caution."* **Authors' research recommendations:** • Address deficiencies in existing study designs as well as assess the impact of gender differences, diet and other lifestyle practices on aerobic capacity. • Follow recommendations of the American College of Sports Medicine

Citation/Objective(s)	Design	Outcome Measures	Findings
			• Standardize TC styles • Represent more diverse study populations, including persons with chronic diseases • Consider other outcomes such as improvement in balance, muscular strength, flexibility, relaxation and mood, and practical utility
Hansen (2006) Cochrane review Massage and TT on anxiety, agitation and depression associated with dementia	Searches of the Specialized Register of the Cochrane Dementia and Cognitive Improvement Group on 12 July 2005 using the terms massage, reflexology, touch and shiatsu **Inclusion criteria:** • RCTs of massage or TT compared with other treatments or no treatment • Outcome measures should be appropriate in the context of the length of the trial and the number of treatments. • Blinded assessment of response • Trials comparing a full massage session with a session containing some of its elements only (e.g. aromatic oil alone) or merely talking to a sympathetic therapist were also included **Quality assessment detailed** **Qualitative synthesis, meta-analysis where appropriate**	Any measures of: • behavioral problems short- or long-term • caregiver burden • survival • medication use • emotional distress • cognitive abilities	N=2 trials, 110 total subjects **Overall results:** • Insufficient data to conduct a meta-analysis. • Limited evidence is available to support the efficacy of two specific applications: the use of hand massage for an immediate and short-term reduction of agitated behavior, and the addition of touch to verbal encouragement to eat for the normalization of nutritional intake. • Overall data are insufficient to draw general conclusions about benefits in dementia. • More methodologically rigorous research with detailed description of randomization procedure, concealed allocation, intervention, and effect parameters is needed.
Joyce (2007) Cochrane protocol Reiki for anxiety and depression	• Trained Usui-initiated Reiki practitioner • Compared with no treatment or placebo Reiki, sham, treatment as usual/waiting list, pharmacological treatment, herbals, exercise therapy, other	• Symptom relief • Beck Depression Inventory (BDI) • Hamilton Rating Scale for Depression (HSRD) • Spielberger State Trait Anxiety Inventory (STAI) • Quality of Life, eg SF12, SF36 • Self-perceived stress • Drop out rates • Side effects • Acceptability of treatment	• In progress
Robinson (2007) Cochrane review TT for anxiety disorders	Searches in 2006 of the Cochrane Collaboration Depression, Anxiety and Neurosis Controlled Trials Registers (CCDANCTR studies and references), the Controlled Trials website and Dissertation Abstracts International, reference lists of retrieved papers, experts contacted. **Inclusion criteria:** • All published and unpublished randomized and quasi-randomized and RCTs comparing TT with sham (mimic) TT, pharmacological therapy, psychological treatment, other treatment or no treatment /waiting list. • Adults with an anxiety disorder defined by	• Anxiety symptoms presented as continuous or dichotomous outcomes: • Using self-rating scales eg. STAI subscale, Penn State Worry Questionnaire, the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS), or BAI • Clinician-rated scales, such as the Hamilton Rating Scale • Subjective assessments of improvement versus no improvement • Acceptability of TT • Adverse effects • Change in use of medication	• No evidence met inclusion criteria

Citation/Objective(s)	Design	Outcome Measures	Findings
	the Diagnostic and Statistical Manual (DSM-IV), the International Classification of Diseases (ICD-10) • Use of validated diagnostic instruments, or other validated clinician or self-report instruments. **Quality assessment detailed** **Qualitative synthesis, meta-analysis where appropriate**	• Use of other support systems.	
Lee (2007) Qigong for hypertension	Searches of MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycInfo, multiple Korean databases, multiple Chinese databases, Qigong and Energy Medicine Database and *The Cochrane Library* 2006, Issue 3 through August 2006, experts contacted for unpublished trials, hand searching of end references. **Inclusion criteria:** • Published and unpublished studies • RCTs • All languages **Quality assessment by 3 reviewers using Jadad scoring** **Meta-analysis performed where possible**	• All-cause mortality • Systolic blood pressure (SBP) • Diastolic blood pressure (DBP) • Lipid profiles	N=12 trials **Overall results** • Low methodologic quality; mean Jadad score=1.2, range 0-3. 2 RCTs described randomization, none described allocation concealment, assessor or subject blinding, only 1 trial detailed drop-outs and withdrawls **Antihypertensives vs. antihypertensives alone:** • A significantly lower incidence of stroke (P<0.05). and mortality (P<0.01) in the qigong group compared to the controls (1 RCT) • Qigonggroups showed a significant lowering of SBP (WMD -12.1mmHg, 95% CI -17.1 to -7.0) and DBP (WMD -8.5mmHg, 95% CI -12.6 to -4.4; Fig. 2) compared with controls (meta-analysis of 4 RCTs) **Qigong vs waiting list:** • QiGong showed a significant lowering of SBP (WMD -18.5mmHg, 95% CI -23.1 to -13.9) (2 RCTs): **Qigong versus exercise:** • No significant difference in SBP (WMD 1.4mmHg, 95% CI -2.6 to 5.4) or DBP (WMD 1.5mmHg, 95% CI -1.0 to 4.1) (2 RCTs) **Qigong + conventional therapy vs. progressive muscle relaxation + conventional therapy (1 RCT):** • No significant difference was found in lowering blood pressure • Quality of life scores favored the qigong group **Authors' conclusions:** *"In conclusion, there is some encouraging evidence of qigong for lowering SBP, but the conclusiveness of these findings is limited. Rigorously designed trials seem to be warranted to confirm the results."*
Lee (2008) Tai Chi for osteoporosis	Searches through March 2007 using MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycInfo, the ClinicalTrials.gov of National Institute of Health and National Research Register, The Cochrane Library 2007, Issue 1, Korean medical databases (Korean Studies Information, DBPIA, Korea Institute of Science and Technology Information, Research Information Center for Health Database, Korean Medline, and Korea National Assembly Library), Qigong and Energy Medicine Database (Qigong Institute, Melon Park, version 7.3) and Chinese databases (China Academic Journal, Century Journal Project, China Doctor/Master Dissertation Full text DB,	% changes in bone parameters (bone mineral content or density (BMD), bone mass, bone metabolism)	N=7 trials included (5 RCTs, 2 CCTs) • Postmenopausal women (N=3 RCTs, N=1 CCT) • Elderly (2 RCTs, 1 CCT • TC sessions 32 – 280, 2-7 sessions per week with duration of 40 min- 60 min per session. **Overall results:** • Mean quality score = 1.57 out of 5, range 0-4 **In postmenopausal women** • N=1 RCT found TC more effective than sedentary lifestyle in preventing bone loss in the ultra distal tibia [tBMD, P=0.005 (−0.53% vs. −1.46%), BMD, P=0.003 (−0.61 vs. −1.58%); distal tibia diaphysis, P<0.001, (−0.39% vs. −1.40%)] • N=2 RCTs found no differences between TC and exercises or calcium supplementation for BMD in the lumbar spine, radius and ulna). • N= 1 CCT (40 women) showed significant positive effects in serum osteocalcin, pyridinoline and deoxypyridinoline with TC from baseline. • Meta-analysis showed no significant effect of TC on BMD change at the spine vs. no treatment (n= 183, WMD, g/cm2 0.02, 95% CI −0.02 to 0.06, P=0.31, heterogeneity: χ2=0.52,

Citation/Objective(s)	Design	Outcome Measures	Findings
	China Proceedings Conference Full text DB). Manual searches of personal files, relevant journals (FACT - Focus on Alternative and Complementary Therapies, from 1996 to 2007), expert contacts for unpublished data, references of retrieved articles, dissertations and abstracts, and the proceedings of the first International Conference of Tai Chi for Health (December 2006, Seoul, South Korea). Multiple search terms used. **Inclusion criteria** • RCTs or CCTs of TC for preventing or treating osteoporosis • No restrictions on population characteristics or language **Quality assessment** performed independently by two reviewers using 0-5 point Jadad score **Qualitative synthesis with meta-analysis** where appropriate		P=0.91, I2=0%). **In elderly women (generally > 65 years of age)** • N=1 RCT showed no difference in total hip BMD in TC vs. resistance training (RT). • N=1 RCT found favorable effects with TC vs. RT on bone metabolism [BAP % concentration, P<0.05 at 6 weeks after, NS at other measurement periods; PYD % change, P<0.05 at 12 weeks after, NS at other measurement periods] • N= 1 CCT of institutionalized elderly subjects showed improved total BMD (spine, femur and intertrochanter, P<0.05) and reduced fracture rate (P<0.01) with TC vs. usual activity **Authors' conclusion:** *"In conclusion, the evidence is not convincing for tai chi in preventing or treating osteoporosis. Currently there are few good quality trials. More rigorous RCTs, larger sample sizes over longer treatment periods, and assessing relevant outcome measures such as balance, falls, and fall-related fractures are required."*
Wang (2009) Systematic review Tai Chi for psychosocial well-being	Searches of MEDLINE, CINAHL, EMBASE, PsycINFO, CISCOM, the Cochrane Central Register of Controlled Trials (CENTRAL) of the Cochrane Library and dissertations and conference Proceedings through August 2008. Search terms listed. **Inclusion criteria:** • RCT • TC as the intervention vs. active or wait list controls • Published in English only **Quality Assessment** using 2 independent reviewers and modified Jadad scale. • High quality score = ≥ 4 **Qualitative analysis with calculation of effect sizes, no meta-analysis**	Any measure of psychosocial well-being: • Depression • Mood • Stress • Anxiety • Sleep disorder • SF-12/36 mental health scores • Others	N= 15 trials with 1,229 participants aged over 18 years with moderate heart failure, chronic symptomatic hip or knee osteoarthritis, HIV/AIDS, depression and healthy sedentary adults using mainly TC of modified *Yang* style of variable doses (1-3 times per week, 40-90 minutes per week for 6 -48 weeks): • Anxiety (N= 8 trials) • Depression (N=8 trials) • Mood (N= 4 trials) • Stress (N=2 trials) • SF-12/36 mental health scores (N=3 trials) • Anger, positive/negative effect, self-esteem, life satisfaction, social interaction and self-rated health (N=1 trial each) **Overall results** • Mean overall quality score= 3.7, range 2-6 (out of 8), indicating insufficient methodological quality. • N=8 trials scored as high quality but these lacked sufficient blinding of outcome assessors; • N=9 trials (60%) provided an effect size estimate or information needed to compute it • Insufficient reporting of dropout rates (2% to 26%), reasons for withdrawls, group baseline similarities, adhering to ITT principles limited results of other trials. • Evidence suggests TC has a significant effect in 13 of 15 trials, especially in the management of depression and anxiety, but only 6 trials were of high quality studies and with conflicting results. **Authors' conclusion:** *"In conclusion, there are some signs that TC can lead to improved psychosocial well-being. However, the evidence is still not strong enough for us to make any conclusive remarks, and no precise and accurate estimates of the effective size can be summarized. More well-designed RCTs on homogenous populations utilizing specific TC instructional technique and style with an appropriate follow-up period of time are required to evaluate the effect of TC on mental health."* **TAP comment:** review did not report on control group characteristics

Citation/Objective(s)	Design	Outcome Measures	Findings
da Silva (2009) Systematic review Yoga for mood and anxiety disorders	To assess the effectiveness of yoga for treatment of mood and anxiety disorders **Searches** of PubMed, Medline and PsychInfo through 2008 using a range of terms for mood and anxiety disorders. No language or publication limited reported. **Inclusion criteria**: All study types of efficacy of yoga. **Types of interventions:** all yoga practices **Comparators:** any **Quality Assessment** using Yatham 2005 for strength of evidence and recommendation standards. **Analysis:** effect sizes calculated where possible using Cohen's d unless otherwise indicated. Response=25% improvement from baseline.	Any measured improvement from baseline	**Overall results** • One open study case series (n=8) suggests improvement in depression and PTSD with Iyengar yoga as augmentation to antidepressants in Vietnam War Veterans with PTSD, and performed better than qi gong. No statistics or raw data provided. • One case series (n=14) Hatha yoga monotherapy significantly decreased depressive and PTSD symptoms in abused women. No statistics or raw data provided • One case series (n=47) Vivekananda yoga monotherapy reduced anxiety, sadness, fear and disturbed sleep in tsunami survivors in short term. No statistics or raw data provided **Limitations:** No RCTs identified. Poor methodological quality of existing evidence prevents firm conclusions. **Author's conclusions:** *"In PTSD, Level 3 evidence suggests the potential benefits of yoga as monotherapy or augmentation to medication, but requires substantiation through RCTs."* [Level 3 = Prospective uncontrolled trial with 10 or more subjects] **Author's Recommendation:** Use as second line option with Level 3 evidence or higher plus clinical support for efficacy and safety **TAP recommendation:** Research with RCTs or controlled studies is needed before recommending yoga an effective treatment option for PTSD.
So Pui (2008) Cochrane review Healing Touch (HT), TT and Reiki for acute and chronic pain relief	Searches of multiple electronic databases, including *The Cochrane Library*, MEDLINE, EMBASE, CINAHL, AMED and others from their inception through June 2008, hand searching reference lists and bibliographies of relevant articles and organizations, experts in TT were contacted. **Inclusion criteria:** • Published and unpublished studies • RCTs and controlled clinical trials • (CCTs) that reported results using sham, placebo or no intervention as controls. • Unblinded or single blinded trials • Adult subjects age 16 + with pain caused by any disease or illness (no healthy subjects) **Quality assessment detailed**	• Pain intensity as measured by various kinds of rating methods such as VAS, numerical rating scale, McGill pain questionnaire, self-reported pain relief or use of rescue analgesia; • Analgesic requirements.	N= 24 trials with 1153 subjects • HT (N=5), TT (N=16) and Reiki (N=3) **Overall results** (Mean Difference; 95% CI)): • Studies of higher quality faired better in detecting a significant effect. • Effect of all TT had on average greater pain relief than unexposed participants using a 0-10 scale (-0.83; -1.16 to -0.50). **Types of pain:** • Greater acute pain relief in the exposed group (- 0.50; -0.86 to -0.14; P = 0.006) • Greater chronic pain relief in the exposed group (- 1.08; -1.62 to -0.55) • Practitioner experience: unable to determine based on small numbers of studies reporting experience • The greatest effect size between treatment and control was found in the Reiki group [-1.24;-2.06 - -0.42], followed by TT [-0.81;-1.19 - -0.43] and HT, which had no significant effect on pain relief [-0.71;-2.27 - 0.86]. **Analgesic usage**: unclear **Other results:** • Clinical significance of these results is unclear. • Placebo effect: None (P = 0.29), based on N=3 studies. • Authors' conclusions: *"Owing to a lack of good quality data and to the heterogeneous nature of the data, the effect of touch therapies on pain relief is inconclusive. Existing data generally favour the analgesic effect of touch therapies. It is unclear whether the experience of practitioners or the types of touch therapies have any effect. Further evaluation is required. No adverse effects were identified."*
Lee (2009) Systematic review (Internal) Qigong for type 2 diabetes	**Searches** of Medline, AMED, British Nursing Index, CINAHL, EMBASE, PsycInfo, 6 Korean Medical Databases, Chinese Medical Database (China National Knowledge Infrastructure: CNKI), Qigong and Energy Medicine Database (Qigong Institutes, CA)	• Glycosylated hemoglobin (HbA1c) • Blood glucose • Blood viscosity • Fasting plasma glucose (FPG) • 2-h plasma glucose (2hPG) • Insulin sensitive index	N= 9 trials included: 3 RCTs, 1 controlled clinical trial (CCT), 5 uncontrolled observational studies (UOS) • 3 RCTs compared qigong + usual care (including drug therapy) with usual care alone. The quality of these RCTs was poor. Their results suggested favorable effects of qigong + usual care on HbA1c ($P < 0.01$), blood glucose ($P < 0.01$), and blood viscosity ($P < 0.05$).

Citation/Objective(s)	Design	Outcome Measures	Findings
	and The Cochrane Library 2009, Issue 1 through March 2009, plus hand searching our own files and relevant journals (FACT—Focus on Alternative and Complementary Therapies, and Research in Complementary Medicine (Forschende Komplementarmedizin). **Inclusions criteria:** • Prospective clinical trials of relative effectiveness of qigong vs. control of proven efficacy • Patients with type 2 diabetes who received qigong alone or combined with other treatments. • All languages • Peer reviewed publications, dissertations and abstracts **Quality assessment** by 3 independent reviews using Cochrane classification of risk of bias **Qualitative synthesis**		• 1 CCT compared qigong with no treatment and failed to show favorable effects of qigong on FPG, 2hPG, HbA1c or insulin sensitivity. • All UOSs reported beneficial effects of qigong on FPG or 2hPG. • None of the trials mentioned adverse effects, method of randomization or allocation concealment, blinding of the outcome assessors, drop-out or withdrawals. **Authors' conclusions:** *"Collectively this evidence is insufficient to suggest that qigong is an effective therapy for type 2 diabetes."* **Authors' recommendations:** *"Future RCTs of qigong for type 2 diabetes should adhere to accepted standards of trial methodology. The studies included in this review showed a number of problems that had been pointed out by other reviews on qigong or tai chi, e.g., expertise of qigong practitioners, the pluralism of qigong, frequency and duration of treatment, employing validated primary outcome measures and adequate statistical tests, and heterogeneous comparison groups. Furthermore, even though it is hard to blind subjects to treatment, employing assessor blinding and allocation concealment are importing for reducing bias."*
vanderVaart (2009) Systematic review Reiki for multiple conditions	Searches of Medline, EMBASE, Cochrane Library through December 2008 **Inclusion criteria:** • Controlled study • Human subjects • Reiki healer used as intervention • English language **Quality assessment detailed** • Modified Consolidated Standards of Reporting Trials (CONSORT) criteria and Jadad quality score used **Qualitative synthesis**	• Various	N=12 trials • 3 studies administered Reiki for physiological symptoms such as stroke recovery, seizure rate and heart rate and 9 studies administered Reiki for psychological symptoms such as anxiety and depression. • 31 different outcome measures were evaluated, none of which were used in more than 3 studies • 5 of 12 were RCTs • Jadad scores: 11 studies rated "poor", 1 "good" • The most important aspects that determine study quality (randomization, blinding, and accountability of all patients) were not well reported • Evidence suggests that the level of training and/or years of experience of the Reiki may correlate with effectiveness. **Authors' conclusions:** *"In order for Reiki studies to be evaluated and accepted based on their stated outcomes, authors need to ensure that the methodological quality and reporting of the study are adequate…To date, based on the poor quality of studies and their reporting, it is currently impossible to draw definitive conclusions about the efficacy of Reiki."*
Lee (2010) Lowering resting blood pressure (BP) in the elderly	Searches through February 2009 of MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycInfo, the ClinicalTrials.gov, six Korean Medical Databases (Korean Studies Information, DBPIA, Korean Institute of Science and Technology Information, Research Information Center for Health Database, KoreaMed, and National Assembly Library), four Chinese Databases (China Academic Journal, Century Journal Project, China Doctor/Master Dissertation Full text, China Proceedings	• Resting systolic and diastolic BP	N=4 RCTs • All subjects were hypertensive or borderline hypertensive. • Modified Yang styles used: duration was 1 hour per session, on average 2-3 sessions weekly from 6 to 52 weeks, except one trial undertook TC 4-5 times week. • Three RCTs employed an additional home-based TC program. • The methodological quality ranged 2–4 out of 5 points. **Results** • Meta-analysis failed to show favorable effects of TC on systolic BP (n = 191, WMD,-2.5 mmHg, 95% CI –5.90 to 0.90, P = 0.15, heterogeneity: t^2 = 0.00, c^2 = 0.62, P = 0.43, I^2 = 0%) or diastolic BP (n = 191, WMD, -1.49 mmHg, 95% CI –3.50 to 0.52, P = 0.15, heterogeneity: t^2 = 0.00, c^2 = 0.53, P = 0.47, I^2 = 0%) compared with physical exercise.

Citation/Objective(s)	Design	Outcome Measures	Findings
	Conference Full text) and The Cochrane Library 2009, Issue 1. The search terms used were: (tai chi OR taiji) and BP. Hand searching of end references of all retrieved articles and the proceedings of the 1st International Conference of Tai Chi for Health (December, 2006, Seoul, South Korea). No language restrictions. **Inclusion criteria:** • RCTs of tai chi of at least 4 weeks duration • Any type of control • Resting BP as an outcome • Participants age ≥ 60 years • Any language • Independent evaluation of tai chi as an intervention **Quality assessment:** Two reviewers using Jadad score **Qualitative synthesis and meta-analysis** where appropriate using Cochrane methods		• Whether these findings reflect equivalence of effects between interventions is yet unclear. • Inadequate baseline testing, variations in intervention may contribute to differences in effects across studies. **Authors' conclusions/recommendations:** *"The evidence for tai chi in reducing BP in the elderly individuals is limited. Whether tai chi has benefits over exercise is still unclear. The number of trials and the total sample size are too small to draw any firm conclusions. Further rigorous RCTs are warranted."* ***TAP comments**:* insufficient reporting of participant characteristics limited the quality of the review.
Logghe (2010) Tai Chi (TC) for fall prevention, fear of falling and balance in healthy older people	Searches of Medline, Cinahl, Psychlit and the Cochrane Database for Systematic Reviews (CDSR) through Jan 31 2009 using the Cochrane Handbook search strategy for RCTs, along with hand searching of references in relevant reviews and identified RCT. **Inclusion criteria:** • RCT • Healthy participants • Aged 50 years or > • One of the interventions was a form of TC, and 5) the article • Published in English, French, German or Dutch **Quality assessment** • Vernhagen delphi criteria list used to produce an overall risk of bias score • ≤4 points indicating a high risk of bias and ≥5 points indicating a low risk of bias. **Qualitative synthesis and meta-analysis** where appropriate	• Falls, • Fear of falling • Balance	N= 9 trials with 2708 subjects included, 71% in community living • Drop-out rates = 2% to 55% • comparing TC with exercise controls or non-exercise controls • Median quality score = 6, range 3-7; N=9 trials ≥ 5 indicating low risk of bias **Overall results:** • Compared with exercise controls, TC participants showed significant improvements in fall rates (N=2 trials, IRR: 0.51, 95% CI 0.38–0.68) and static balance (N=2 trials, SMD: 0.47, 95%CI 0.23-0.72). Evidence for effects of TC on dynamic balance was conflicting and inconclusive. • Compared with non-exercise controls, TC participants showed no significant difference in fall rates (N=5 trials, IRR: 0.79, 95% CI 0.60– 1.03 but substantial heterogeneity I^2 68.6%) or static balance (N=2 trials, SMD: 0.30, 95% CI −0.50–1.10). TC showed a significant improvement in fear of falling (SMD: 0.37, 95% CI=0.03–0.70), which became non-significant in all subgroups, except in the subgroup high intervention dose (> 40 sessions) where the effect increased and remained significant (SMD: 0.54, 95% CI=0.29–0.78). • Evidence for effects of TC on dynamic balance was conflicting and inconclusive. **Authors' conclusions:** *"Currently, there is insufficient evidence to conclude whether TC is effective in fall prevention, decreasing fear of falling and improving balance in people over age 50 years. However, the presence of a positive dose–effect relation in TC is highly likely. Future research should focus on the role of patient characteristics (e.g. living setting, activity level), intervention dose and effect maintenance on the measured outcomes."*
Gorcznski (2010) Exercise therapy for schizophrenia (only yoga reported)	Searches of Cochrane Schizophrenia Group Trials Register (December 2008), which includes systematic searches of major databases, hand searches and conference proceedings. Search terms detailed. **Inclusion criteria:** • RCTs • Diagnosis of schizophrenia or	Assessments of mental and physical health, and health care utilization and cost.	N=1 trial with 61 subjects in a hospital setting comparing the effects of a 16 week light exercise program (n=30) with usual care + yoga (n=31) **Overall results:** • Improved mental state with usual care + yoga (PANSS total: 1RCT, n=41, MD 14.95 CI 2.60 to 27.30). • Significantly better QoL scores with usual care + yoga group (WHOQOL Physical: 1RCT, n=41, MD -9.22 CI -18.86 to 0.42). • Similar adverse effect scores (AIMS total scores)

Citation/Objective(s)	Design	Outcome Measures	Findings
	schizophrenia-like illnesses using any criteria or severe mental illness likely to be schizophrenia • Any length of illness • In any treatment setting. • Any age, nationality or gender of participants. • Physical activity or exercise was considered to be the main or active ingredient compared with standard care or other treatments of a similar duration **Quality assessment detailed based on** Cochrane Reviewer's Handbook **Qualitative synthesis**		• Drop outs = 20 (33%) **Authors' conclusions:** Exercise programs with yoga are feasible in people with schizophrenia. Regular exercise with yoga can produce positive physical and mental health effects and improved well being. **Authors' recommendations:** Larger randomized studies are required before any definitive conclusions can be drawn.
Hróbjartsson (2010) Cochrane review Placebo interventions for all clinical conditions **[included for discussion only]**	Searches of Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* Issue 4, 2007), MEDLINE, EMBASE, PsycINFO and Biological Abstracts through March 2008, experts on placebo research, and hand searched references in the included trials. **Inclusion criteria:** • Clearly randomized placebo trials with a no-treatment control group; • For any health problem eg. any somatic or psychiatric disease or symptom; • Observer blinded to group assignment • Drop-out rate ≤ 50% **Quality assessment detailed** • Standardized data chart used • Meta-analyses conducted	• Various continuous and binary outcomes • Four areas were investigated in at least three trials with binary outcomes: nausea, pain, relapse in preventions of smoking, depression • Eleven clinical problems were investigated in at least three trials with continuous outcomes: anxiety, asthma, dementia, depression, hypertension, insomnia, nausea, overweight, pain, phobia, and smoking	**N=202 trials suitable for meta-analysis** 44 trials (N=6041) with binary outcomes reported as relative risk (RR), 95% confidence interval (CI): • Overall pooled effect of placebo: RR 0.93, 0.88 to 0.99. • No difference between patient-reported (Pooled RR 0.93, 0.86 to 1.00) and observer-reported (Pooled RR 0.93, 0.85 to 1.02) outcomes • No statistically significant effect of placebo interventions in pain, nausea, smoking, and depression, but confidence intervals were wide. • The effect on pain varied considerably, even among trials with low risk of bias. 158 trials (N=10,525) with continuous outcomes reported as standardized mean difference (SMD), 95% CI): • Moderate heterogeneity ($P < 0.001$; I^2 42%), and considerable variation in effects between small and large trials (higher effects in smaller trials), pooling done to identify reasons for heterogeneity • Modest pooled effect on patient-reported outcomes (SMD 0.26, -0.32 to -0.19) • Small and uncertain pooled effect on observer-reported outcomes (SMD -0.13, -0.24 to -0.02). • Variable effect on pain (SMD -0.28, -0.36 to -0.19), also among trials with low risk of bias • Small, but consistent effect on nausea (SMD -0.25, -0.46 to -0.04) • Uncertain effect on asthma (SMD -0.35, -0.70 to -0.01), due to high risk of bias • Uncertain effect on phobia (SMD -0.63, -1.17 to -0.08), due to high risk of bias • No statistically significant effect of placebo interventions in the seven other clinical conditions investigated in three trials or more: smoking, dementia, depression, obesity, hypertension, insomnia and anxiety, but confidence intervals were wide. **Conclusions:** *"We did not find that placebo interventions have important clinical effects in general. However, in certain settings placebo interventions can influence patient-reported outcomes, especially pain and nausea, though it is difficult to distinguish patient-reported effects of placebo from biased reporting. The effect on pain varied, even among trials with low risk of bias, from negligible to clinically important. Variations in the effect of placebo were partly explained by variations in how trials were conducted and how patients were informed."* *"Most clinical placebo prescriptions involve deceit and the effect of placebo has not been tested in trials after full disclosure that the patients receive placebo. Therefore, we suggest that placebo interventions are not used outside clinical trials."* *"Further research is needed to study the impact of bias (such as response bias and bias due to*

Citation/Objective(s)	Design	Outcome Measures	Findings
			co-intervention) on the estimated effect of placebo, to study the association between type of outcome and bias, to explore which factors in the clinical setting are associated with different effects of placebo, and to explore the duration of effects."

Table 5. Randomized controlled trials of energy therapies included in this report

Study Attributes	Aghabati (2010)	Korn (2009)	Woods (2009)	McCormack (2009)
Study objective	To study the effect of TT on pain and fatigue in cancer patients undergoing chemotherapy	Polarity therapy (PT) versus enhanced respite control condition (ERC) to reduce stress and depression and improve quality of life in Alzheimer's Disease caregivers	TT vs. placebo vs. controls for reducing behavioral symptoms of dementia (BSD) and basal cortisol levels among NH residents with dementia.	Effectiveness of non-contact therapeutic touch (NCTT) on post-surgical pain in elderly receiving occupational therapy (OT)
Study size	N=90 (30 TT, 30 placebo, 30 usual care)	N=42 (21 PT, 21 ERC)	N=64 (22 TT, 21 placebo TT, 21 control)	N=90 (30 NCTT, 30 "placebo", 30 control)
Perspective	Prospective	Prospective	Prospective	Prospective
Recruitment source	• Convenience sample from three hospital special care units • All females	• Community based • Western Washington State Native American or Alaskan Natives	• Nursing home residents • Southern US • N=170 screened, 85 met inclusion criteria	• Convenience sample from an acute care hospital unit in the US
Inclusion criteria	• Cancer diagnosis • Normal level of consciousness (Glasgow Coma Scale = 15) • Ages 15-65 • Resided in unit for at least 5 days • Only females	• Primary caregiver of family member with dementia for ≥ 6 mo. • Provides ≥ 4 hrs of direct assistance/day • Telephone access • Staying in community for ≥ 6 months.	• Age ≥ 65 years, • Diagnosed with moderate to severe dementia (DSM-IV criteria) • NH resident for ≥ 2 months • On a stable regimen of medications (including psychotropic medications) for ≥ 1 month, • Able to ambulate (by walking or wheel chair), • Brief Agitation Rating Scale (BARS) score ≥ 15 • Mini Mental State Examination Scores < 25 • All exhibited BSD	• Medically stable • Cognitively intact • Willing to volunteer
Exclusion criteria	• Any other diseases that may cause pain	Medical conditions that would preclude the use of PT eg. acute infection, DVT, diabetic neuropathy, current substance abuse, cardiac arrhythmia etc.	• Acute psychiatric or physical • illness, • A new diagnosis of dementia (within 3 months), • End-stage dementia (as determined by a medical practitioner).	Not reported
Characteristics of study subjects	• Comparable baseline characteristics with respect to age, education level, having a career at home, social support resources, surgery treatment, chemotherapy sessions, stage of cancer, and length of pain suffering • Comparable with respect to type of cancer, narcotic analgesic use, and interval between to chemotherapy periods, but data not reported	• Ave age= 50 years (range 27-69 years); 90% were women: 52% daughters, 10% wives, 7% sons, and 31% other relatives. • No statistically significant difference between baseline and post-treatment re caregiver perceived stress, depression, QoL, sleep quality, worry, & physical health	• Age 67–93 years (M = 85.5, SD = 5.50) • Male/female = ~ 1:4 • 96% Caucasian • 80% Married or widowed • Did not differ significantly at baseline with respect to age, gender, type of dementia, MMSE score, medication use, comorbidities, and activities of daily living (ADL) scores	NCTT group: • 11 males, 19 females • Age 47- 90 years, mean=72.27 years. Placebo group: • 12 males,18 females • Age 28-96 years, mean= 74.07 years Control group: • 14 males,16 females • Age 44–95 years, mean= 71.67 years. • All three groups were similar in ethnic diversity. The surgeries across groups were primarily orthopedic: total hip and knee replacements were most common. • Similar day-to-day post-surgical treatment • Statistical similarity not reported
Random assignment	• Yes, procedure detailed using numbered cards and pockets representing the study groups	• Yes, not detailed • Plus stratified based on stress level score	• Yes, random numbers table used	• Yes, but not detailed

Study Attributes	Aghabati (2010)	Korn (2009)	Woods (2009)	McCormack (2009)
Intention-to-treat analysis	• Yes, all subjects were accounted for in the analysis	• Yes • 38 of 42 analyzed • 4 drop outs had similar baselines (reason for drop out=time constraints)	• 1 drop out due to becoming agitated by continued observation	?
Intervention(s)	• TT group: delivered once per day for 5 days between 10:00am and 10:30am) • Placebo=mimic TT using same movements as TT but counting back from 100 by serial sevens • Control=routine intervention in the ward	• 8-50 min sessions of standardized PT (21 point protocol with experienced practitioners) • 8 sessions 60-120 min of ERC	• Standardized contact TT protocol delivered twice a day for 3 days at the same time each day (between 10:00 and 11:30 a.m. and 3:00 and 4:30 p.m.) lasting 5–7 min by 3 research assistants, with 5–8 years experience • Same protocol for placebo performed by 3 research assistants, blinded to the purpose of the study, and with no previous knowledge of TT • Control received standard care	• Non-contact TT: 10-minute administered by a skilled occupational therapy graduate student trained by the principal investigator. • Intervention 2: 10-minute exposure to a metronome at 60 beats per minute. • Control: standard post-surgical care
Follow up	• Time 1=first day of treatment • Time 2=second day of treatment • Time 3=third day of treatment • Time 4=fourth day of treatment • Time 5=fifth day of treatment	• Baseline • End of treatment sessions (8 weeks)	• Baseline (B) = 4 days, • Treatment 1 (T1) = 3 days • Post-treatment 1 (P1) = 5 days • Treatment 2 (T2) = 3 days • Post-treatment 2 (P2) = 5 days).	• Pre-treatment • Immediately post-treatment
Outcome measures	Self reported measures in TT and placebo groups of: • Pain (Visual Analog Scale (VAS)) • Fatigue (Rhoten Fatigue Scale (RFS)) • Mean of difference before and after intervention on each day was determined in TT and placebo groups but not in control group	• Physical exam • Self-reported measures: • Perceived Stress Scale (PSS) • Center for Epidemiological Studies-Depression Scale (CES-D) • SF-36 • Quality of Life-Alzheimer's Disease (QoL-AD) • Pittsburgh Sleep Quality Index (PSQI) • Penn State Worry Questionnaire (PSWQ)	Behavioral measures • *Brief Agitation Rating Scale (BARS)* • *Mini Mental State Examination (MMSE)* • *Modified Agitated Behavior Rating Scale (mABRS)* • Overall BSD and 6 categories of BSD • Salivary cortisol at waking, after 30 min, after 6 h and after 12 h.	• Memorial Pain Assessment Card (MPAC) (for pain intensity, pain relief) • Tellegen Absorption Scale (TAS) (for absorption levels or openness to experience) • Health Attribution Test (HAT) (for health belief and locus of control) • Relaxation: Pulse rate and pupil size
Blinding	• Subjects blinded to TT or placebo group but not to control • Researcher not blinded to treatment allocation • Researcher=treatment practitioner or unclear	• Caregivers not possible to blind • Assessors blinded to treatment allocation	• Double blind (masked), 3-group, experimental interrupted time • Series ABAB	• Assessor blinded to treatment allocation • Subjects not blinded to treatment; placebo not at true placebo
Results	**Efficacy: Pain Scores** • ANOVA showed significant differences between the three groups within the 5 days of intervention (F=2.01, df=8, P=0.04, n=90) • Tukey HSD test showed significant difference between the TT and placebo groups in each of the five days, and between the TT and control groups in each of the five days • Tukey HSD test showed no significant difference between placebo and control groups at Time 1 but significant differences at Times 2 through 5. **Efficacy: RSF Fatigue Scores** • ANOVA showed significant differences between the three groups within the 5 days of intervention (F=3.18, df=8, P=0.002, n=90)	• Outcomes improved significantly more using PT than ERC on stress (p = .01), depression (p = .045), bodily pain (p = .02), vitality (p = .03), and general health (p = .01). • Multivariable analysis confirmed findings. • No serious adverse events reported	• Only restless behavior decreased significantly by group (F2,61= 3.03, p = 0.05) and time (F4,230 = 11.04, p < 0.0001) • Mean behavior score at baseline was lower in the TT, compared with placebo or controls, but not statistically different • No significant group by time interaction (F8,230 = 0.77, p < 0.63). • Pairwise comparisons showed a significant difference in restlessness between TT group vs. control group (p = 0.03) at P2 but not at T1 or P1. • No significant difference in restlessness between TT vs placebo or placebo vs. controls. • A decreasing trend of restlessness from B to	**Mean pain intensity scores:** • NCTT: pre-test (M =44.57) to post-test (M =30.97) [(t [7] =7.24, p < 0.01]. • Intervention 2: pre-test (M =22.70) to post-test (M =25.23), NS • Controls: pre-test (M =45.23) to post-test (M =45.30), NS. **Mean pain word scores:** • NCTT: pre-test (M =4.23) to post-test (M =3.47); (t =4.95, p < 0.01). • Intervention 2 and controls trended upward post-test **Mean pain relief scores:** • Pre-test: no statistically significant difference between groups • Difference in NCTT pre-test and post-test

Study Attributes	Aghabati (2010)	Korn (2009)	Woods (2009)	McCormack (2009)
	• Tukey HSD test showed a significant difference between the TT and placebo groups in each of the five days, and between the TT and control groups in each of the five days • Tukey HSD test showed no significant difference between placebo and control groups at Times 1, 4 or 5 but there were significant differences at Times 2 and 3.		T2 observed in all groups • There was a significant NH effect for morning cortisol (F = 3.56, p = 0.03). • No significant differences between NH with respect to diagnostic category (AD), MMSE, ADL, mobility, and medications used • A significant NH difference in the number of comorbidities was found (F = 4.17, p = 0.02). • Within-person mean daily cortisol values had a significant time effect (F2,51 = 2.93, p = 0.02), but no significant group effect and no group by time interaction.	relief scores was statistically significant (*t* [2] =3.10, *p* <0.05). • Difference in intervention 2 pre-test and post-test was statistically significant (*t* [2] 6.083, *p* 0.01). • No statistically significant difference pre-test and post-test in the control group. **Mood, pupil size or pulse rate** • No statistically significant difference between groups pre-test and post-test. • No significant difference between the post-test pain relief scores and the post-test high and low scores on health belief profiles (*t* [26] = −0.938, *p* = 0.357). • No significant relationships found between measures of health belief scales, measures of pain intensity and measures of relaxation.
Authors' conclusions	• The results suggest that TT was more effective in decreasing pain and fatigue of the cancer patients undergoing chemotherapy than the usual care group, while there was a decreasing trend in pain and fatigue scores in the placebo group compared with the usual care group, indicating a placebo effect • Interpreting the placebo intervention as compassionate touch, one-one social interaction or nursing presence may explain a decrease in pain and fatigue of cancer patients in the placebo group. • Future research should include physiologic correlates to explain the mechanism of action of TT, conditions under which TT is most effective and the role of TT in deceasing depression, anxiety and stress in cancer patients.	*"These results indicate that the delivery of PT to AI dementia family caregivers is feasible and culturally acceptable and may be an important approach to reducing stress, depression, and pain."*	• *"Findings suggest that therapeutic touch may be effective for management of symptoms like restlessness coupled with stress reduction."* • *"…variation in comorbidities may be one of several factors that account for the differences in cortisol and behavior in the three NH."*	• *"The results of the data analysis showed that the group who received NCTT had statistically significant reductions in pain intensity when compared with the mean scores of the placebo and control groups."* • *"…While Western medicine attempts to develop new pharmacological solutions for pain, NCTT may play a non-invasive role in managing post-surgical pain..."* • *"Further research is recommended to replicate this study."* **Limitations** • TAS may not be sensitive enough to use on the elderly population. • Pulse rate and pupil size were not accurate measures of relaxation; other measures of physiological responses are needed • Most subjects used Vicodin (Abbott Laboratories,Illinois), which can chemically alter mood and affect results. • Convenience sample used • A visual analogue scale may be inappropriate for use in an elderly population • Inexperienced practitioner of NCTT • More appropriate quality of life measures could have been employed post-discharge.
TAP notes	• Power calculations performed using Nomogram's Altman (clinical difference=2, standard error=3 and power (1-β)=0.90 • Need more detail on narcotic analgesic use		**Limitations:** • Underpowered, therefore unable to discriminate between treatment and placebo effect	• Change in medication use not measured • Not a true placebo • Short follow up, more data points needed • Expectation not controlled for

Study Attributes	Aghabati (2010)	Korn (2009)	Woods (2009)	McCormack (2009)
	among subjects in relationship to the intervention • Investigator was also practitioner, therefore not blinded to treatment allocation • Authors stated that: *"We did not use test-retest technique* [in the control group] *because patients' pain and fatigue could vary in two different times"* but such variation could be possible among all groups.		• Homogeneous population (female Caucasian) • Medication use not controlled for	

Table 5 (continued)

Study attributes	Assefi (2008)	Walach (2008)	MacIntyre (2008)	Hawranik (2008)
Study objective	Effectiveness of Reiki as treatment for fibromyalgia	Effectiveness of distant healing in stable chronic fatigue syndrome (CFS)	To evaluate the efficacy of healing touch (HT) on outcomes of coronary artery bypass (CAB) surgery	To study the effect and duration of touch therapy (TT) on agitation associated with Alzheimer's disease (AD)
Study size	N=100 (25 Reiki direct, 25 Reiki distant, direct placebo, distant placebo)	N=409: • 105 blinded + healing • 102 unblinded + healing • 95 blinded + no healing • 109 unblinded + no healing	N=237 (87 HT, 87 controls, 63 visitor) N=117 outpatients, 120 inpatients	• N=51 (17 TT, 16 simulated TT, 18 usual care)
Perspective	Prospective	Prospective	Prospective	Prospective
Recruitment source	• Community based • Seattle, Washington metropolitan area between April 2003 and September 2004.	• Community based • Between October 2001 and May 2003 from 14 private practices in Germany and Austria by doctors that specialized in CFS and who use integrative medicine treatment approaches • N > 1400	• Consecutive outpatients in a community hospital in St. Paul, MN from Sept 1999 to Nov 2002 • In May 2000, non-emergent inpatients were added to speed enrollment • N=601 total of which 163 did not meet inclusion criteria, 123 declined, 25 had insufficient time between eligibility assessment and scheduled surgery	• Permanent, medically stable residents from personal care and special needs units of a long-term care facility
Inclusion criteria	• English speaking • Age ≥ 18 years old • physician diagnosis of fibromyalgia • Global pain score of ≥ 4 • Willing to be randomized • Constant dose of pharmacological and nonpharmacological therapies for fibromyalgia throughout the study • Use of only acetaminophen and ibuprofen for breakthrough pain.	• Age ≥ 18 years of age • Clinically diagnosed with chronic fatigue or CFS	• Subjects undergoing first-time elective CAB • Competent to answer questionnaires	• Diagnosis of senile dementia of the Alzheimer's type • MMSE score ≤ 23 • Age ≥ 65 yrs • History of agitated behavior or consistent agitated behavior during the past month • Residence on unit ≥ 2 mo • Absence of acute illness during study • Written/verbal consent
Exclusion criteria	• Other pain-related medical conditions • Pregnant or breastfeeding, • Used narcotics • Involved in ongoing litigation related to their fibromyalgia or receiving disability payments • Lived > one hour away from the research center • Unable to attend 8 weeks of biweekly therapy • Previously received any energy therapy (to maximize blinding).	• Other chronic conditions or co-morbidity that typically rules out a diagnosis of CFS • Pregnancy • Serious or acute illness or hospital admission in the 3 months prior to entry.	• Subjects undergoing valve or minimally invasive CAB • History of CAB • Emergent CAB patients	

Study attributes	Assefi (2008)	Walach (2008)	MacIntyre (2008)	Hawranik (2008)
Characteristics of study subjects	• Mean age 49 years • 92% women • 80% white • 53% with a college degree • 43% married. • Almost half of participants reported being sure that Reiki could relieve the symptoms of fibromyalgia. • Similar baseline demographic characteristics, clinical features, and treatment expectations across the 4 treatment groups.	Balanced baseline characteristics with respect to (but statistical significance not reported): • Age • % female • Education level • Unemployment history • Duration of CFS • % severe idiopathic CFS • Fatigue severity score • Credibility and expectancy of distant healing • Belief in CAM • Religious beliefs	• Comparable baseline except for pre-op anxiety scores (HT=41, visitor=41, control=45, *P*=.04) • Ave age: HT=64, Visitor=66, Control=64 • % Female: HT=79.3%, Visitor=74.6%, Controls=77% vs. general CAB population=23.1%	• Comparable baseline characteristics with respect to male:female, mean age (82.8 yrs), length of time on unit (30.2 mo), number of diagnoses (4.0), number of medications (6.4), MMSE (5.5), number of physically aggressive behaviors displayed, number of physically nonaggressive behaviors, number of verbally agitated behaviors displayed
Random assignment	• Yes, using a computer-generated blocked random allocation sequence with a block size of 4. • Coordinator blinded to treatment allocation	• Yes, concealed computer-generated coding	• Computerized randomization • Allocation in blocks of 6	• Yes, but not detailed
Intention-to-treat analysis	• Yes • 7 drop outs prior to receiving any therapy • 12 drop outs after receiving 1–8 treatments. • Most common reason = other time commitments	• Yes	• No; N=290 randomized, 237 completed the study	• No
Intervention(s)	• Standard Reiki and sham protocols delivered 2 30-minute treatments weekly for 8 weeks (16 treatments). • 75% completion or better=full course	• Allocated to 4 groups of 3 healers from a pool of 462 healers in 21 European countries with different healing traditions. • Blinded + healing • Not blinded + healing • Blinded + no healing • Not blinded + no healing • "Blinded" refers to the subject were unaware of treatment allocation • "Healing" refers to subject told they would receive immediate healing tx versus deferred waiting for 6 months	• HT=pre-op education + various techniques from same practitioner for Time 1 and 3 ranging from 20 to 60 min + 60-90 min Time 2. • Visitor nurse=3 visits with standardized conversation • Control=standard CAB protocol	• First week: Usual care (control) • Second week: Simulated TT 30-40 min treatment X 5 consecutive days split between two different volunteers trained in a simulated technique • Third week: TT 30-40 min treatment X 5 consecutive days split between two different TT practitioners
Follow up	• Baseline (week 0) • Midway (week 4) • End (week 8) • 3 months after completion of treatment (week 20).	• Baseline • At 6 months • 18 months follow up	• Time 1=day before surgery • Time 2=day of surgery • Time 3=day after surgery	• Time 0=Baseline • Time 1 to Time 5=2 hours post each treatment • Time 6=24 hours post final treatment • Time 7=1 week post final treatment • Time 8=2 weeks post final treatment
Outcome measures	• Subjective pain during the previous month using 10-cm visual analog scale (VAS) • Medical Outcomes Study 36-item Short-Form Health Survey • Short Form-36 physical and • Mental component scales • Medication use over time • Utilization of allopathic or CAM practitioners	• Primary outcome measures: • Mental Health Component Summary (MHCS) score SF-36 (self-reported mental health) • Physical Health Component Summary (PHCS) score SF-36 (self-reported physical health)	• Post op LOS • Incidence of post-op atrial fibrillation • Use of anti-emetic meds • Amount of narcotic pain meds normalized to a morphine-equivalent dose • Functional status (SF-12) recorded pre-op and 6 mo post-op • Anxiety (State Trait Anxiety Inventory (STAI))	• Physical aggression, physical nonaggression, and verbal agitation based on primary nurse observation with research assistant • Cohen-Mansfield Agitation Inventory (CMAI) for measuring 29 agitation behaviors

Study attributes	Assefi (2008)	Walach (2008)	MacIntyre (2008)	Hawranik (2008)
Blinding	• Reiki and sham practitioners could not be blinded to treatment group • All research personnel were blinded to treatment group • Adequacy of blinding assessed by subjects rating skill level of provider, belief that they had received Reiki or sham over the course of the study using a 5-point scale (≥ 3 as endorsement), and changes in anxiety levels at 4, 8, and 20 weeks	• Investigators blinded to treatment allocation • Half study subjects were blinded to treatment allocation	None	• Subjects, their legal designate, the staff, the volunteers administering the simulated TT, and research assistants blinded to the group assignment. • Investigators and TT practitioners unblinded to group assignment.
Results	• Adverse effects: o 38/93 (41%) reported excess energy or feelings of anxiety o 17/93 (18%) reported other eg. worsening of sleep and depressed mood. o Not associated with provider assignment or treatment type • No VAS or functional outcome differed between the 4 treatment groups during or following the interventions. • No treatment factor main effects were significant for any outcome.	• Trial population had very low quality of life and symptom scores at baseline **Effect (SE); 95% CI**: • No differences over 6 months in post-treatment MHCS scores between groups. • Non-significant outcome for healing with PHCS (.11(0.69); –0.255 to 2.473; p = 0.11) at 6 months • Significant effect for blinding (-0.54 (0.70); -2.91 to -0.18; p = 0.027) • Unblinded patients became worse during the trial (–1.544; 95% CI –2.913 to –0.176). • No relevant interaction for blinding among treated patients in MHCS and PHCS. • Expectation of treatment and duration of CFS added significantly to the model.	Statistically significant results (P< 0.05) • Adjusted mean LOS: lower in HT group than in the other two groups [HT=6.9 days (95% CI=6.1, 7.7) vs. Visitor=7.7 days (95% CI=6.7, 8.7) vs. Control=7.2 days (95% CI=6.4, 8.1) (P=.04)] • Mean outpatient LOS: lower in HT group than other two groups [HT=6.6 days (95% CI=5.2, 7.5) vs. Visitor=7.4 days (95% CI=6.0, 9.0) vs. Control=7.7 days (95% CI=6.0, 8.6) (P=.01)] • HT showed greater decrease in anxiety scores vs. other groups [HT=6.3, Visitor=5.8 vs. Control=1.8; P=.01] • No adverse events reported in HT group • No significant differences between groups found in other outcome variables	**Comparison across groups:** *Time 0 (baseline) to Time 5:* • No significant difference in the incidence of physically aggressive (X^2 = 2.28, p = .32) and verbally agitated behaviors (X^2 =1.99, p = .37). • Significant differences in incidence of physically nonaggressive behaviors (X^2 = 5.98, p < .05): 2.3 times > in the usual care group than the TT group (CI .66, 7.81) and 0.8 times > in simulated TT group than TT group (stats not reported) *Post-intervention—Time 6 to Time 8:* • No significant difference in incidence of physically aggressive behaviors (X^2 = 1.35, p = .51); physically non-aggressive behaviors (X^2 = 1.37, p = .51); verbally agitated behaviors (X^2 = 3.14, p = .21). **Comparison across time:** *From Time 0 to Time 5:* • There was a significant decrease in the incidence of physically aggressive behaviors (X^2 = 24.53, p < .001), physically non-aggressive behaviors (X^2 = 28.18, p < .0001) and verbally agitated behaviors (X^2 = 31.94, p < .0001) in all three groups. *From Time 6 to Time 8:* • There were significant increases in the physically aggressive and nonaggressive behaviors (X^2 = 10.63, p < .01; incidence ratio = .29, CI .13, .65 and X^2 = 11.03, p < .01; incidence ratio = .52, CI. 36, .77, respectively) in all three groups. • No significant differences in verbally agitated behaviors (X^2 = .62, p = .73) in all three groups. *From Time 0 to Time 8* • Data not presented
Authors' conclusions	*"Our randomized controlled trial of Reiki for fibromyalgia suggests that adults with*	• *"This rigorously designed, randomized controlled and partially blinded trial in patients*	• There were significant decreases in anxiety scores in the HT subjects and in length of stay	• During treatment, there was a significant decrease in the frequency of physically

Study attributes	Assefi (2008)	Walach (2008)	MacIntyre (2008)	Hawranik (2008)
	fibromyalgia are unlikely to benefit from Reiki. Future Reiki trials should require blinding of participants and staff who handle data as well as thoughtful construction of control and placebo interventions—no easy feat considering our nebulous understanding of energy medicine therapies."	*with CFS showed no significant effect for distant healing in MHCS (SF36) and a small effect in PHCS (SF36) which might be due to patient expectation. In addition, we found little evidence for a blinding/treatment interaction, although those who knew they were not being treated recorded poorer outcomes for the PHCS scores. Our post hoc analysis suggests that the most important clinical effects of distant healing may be related to patients' beliefs about whether they received treatment."* • *"We suggest that future studies on spiritual healing particularly focus on the healer-patient relationship and the importance of belief as well as investigating the specific therapeutic effects using different methodological approaches such as qualitative research and N-of-1 trials."* **Limitations** • Generic quality of life measures used may lack sensitivity to subtle changes of QOL in the study population. • No additional outcome measures are available	among outpatient HT subjects, compared to the other groups	nonaggressive behaviors such as pacing, repetitious movements and general restlessness, in all three groups, but more of a decrease observed in the TT and simulated TT groups than usual care; neither strategy had an effect on physically aggressive behaviors • After treatment, the frequency of all three behaviors gradually increased over a two-week period in all groups, but remained less than baseline levels, however the statistical difference between Time 0 and Time 8 was not reported • *"Additional research is needed to overcome the limitations in this study, such as small sample size, reliance on a number of different staff nurses who may not know the resident, and the need to examine other behaviors. Future research with larger study samples, conducted at another time of year and time of day, and actual observation of behaviors by research staff before and after intervention may provide more data on the efficacy of TT. Exploring the mechanisms of TT and its relationship to the various behaviors and varying severities of dementia should be considered."*
TAP notes	• Power calculations performed	• Power calculations performed	• Power calculations yielded total N=402 with power=0.8, α< 0.05, detectable change of 0.5 days in LOS • Recruitment stopped due to recruitment difficulties, impending changes to care protocols and interim analyses that suggested additional enrollment was unlikely to yield more statistically significant findings • Why was % females in the study population much higher than in the general CAB population?	• Power calculations yielded an *N*=60, (20 per group) to obtain at least a "medium-sized effect" at p=0.8, but changes in health, relocation to other facilities, death, and difficulty in identifying residents with agitated behavior prevented attainment of the desired sample size.

Table 5 (continued)

Study attributes	Nourbakhsh (2007)	Pippa (2007)	Dowd (2007)	Elder (2007)
Study objective	To study the effects of Oscillating-energy Manual Therapy (OEMT) on chronic lateral epicondylitis (LE)	To examine the efficacy of Qigong(QG) exercises on improving functional capacity in patients with stable chronic atrial fibrillation (AF) and preserved left ventricular (left ventricular) function.	To study the effectiveness of HT, coaching, and a combination of both on generalized stress	To determine the feasibility and clinical impact of Qigong, Tapas Acupressure Technique® (TAT) and self-directed support (SDS) for weight-loss (WL) maintenance
Study size	• N=23 (11 OEMT, 12 placebo)	N=43 (22 QG, 21 wait-list control)	• N=58 • Power analysis: 14 evaluable data sets required in each group to achieve significance; 0.80, α =.10.	• N= 92 (31 Qigong, 30 TAT, 31 SDS) • Power analysis: 30 subjects per group would have power 85% to detect large effect size of 0.77
Perspective	Prospective	Prospective	Prospective	Prospective
Recruitment source	• Northeast Georgia community based • Time period not noted • Source population not detailed • Diagnosis confirmed by orthopedist	• 47 former inpatients at Hospital of Lanciano, Italy between January 2004 and February 2005 • Eligibility determined by cardiologist chart review, ultrasonography • Convenience sample?	• University Health Services and the Center for Nursing in the College of Nursing at a Midwest state university • Fall 2005 and spring 2006	• Community and employees of Kaiser Permanente Northwest (N=223) • May-September 2004 • BMI requirements: Women BMI=25-35 kg/m^2; Men BMI=25-40 kg/m^2 • N=101 deemed eligible for WL maintenance program
Inclusion criteria	• Diagnosed with unilateral LE	• Diagnosed with AF at least 3 months prior • On anticoagulant treatment for at least 2 months.	• University students • Full-time or part-time • Aged 18 to 24, • Self-identified as having stress-related discomforts such as transient headaches, anxiety, difficulty concentrating, insomnia, and appetite changes (overeating or undereating).	• Ages 18-80 • Live in Portland metropolitan area • Completed the WL program, attended 75% of WL sessions, lost at least 3.5 kg in the WL program, willing to be randomized to 1 of 3 arms • Signed consent
Exclusion criteria	• Proximal upper extremity or neck symptoms • History of cervical pathology, nerve entrapment syndromes, nonunion fractures • Surgery for LE • Steroid injection for elbow pain during the last six months	• Ejection fraction <30% and/or New York Heart Association class III–IV • History or suspicion of a recent thromboembolic event • Recent heart rate instability or other indication for EKG monitoring during exercise training • Chronic systemic diseases in the acute phase • Bone or joint conditions limiting exercise training • Major logistic impairments • Involvement in regular training programs • Inability to give informed consent.	• Diagnosed with psychiatric illnesses or migraine headaches • Currently treated for stress • Aged 25 or older • Unable to keep required appointments, and/or complete the follow-up questionnaire at 1 week post study.	Medical conditions or treatment that may contraindicate using a diet and exercise WL treatment, including: • Cancer • Significant gastrointestinal disease inappropriate for diet and physical exercise intervention • Diabetes • Hypertension meds • High cholesterol meds • Psychiatric hospitalization during previous 2 yrs • Meds for psychosis or manic-depression • Congestive heart failure • Cardiovascular disease • Concurrent use of WL meds or within the previous 6 months • Liposuction in the previous 12 months • History of bariatric surgery • History of previous CAM WL treatment, current acupuncture, acupressure or qigong

Study attributes	Nourbakhsh (2007)	Pippa (2007)	Dowd (2007)	Elder (2007)
				use • Planning pregnancy or presently pregnant during study • Household member of another participant in study
Characteristics of study subjects	• Comparable baseline characteristics with respect to pretreatment grip strength (p=0.22), pain intensity (p=0.85), functional level (p=.89) or pain limited activity level (p=0.80) • Mean duration of symptoms> 12 months • All reported previous unsuccessful treatment with rest, physical therapy, and cortisone injections	• Comparable baseline characteristics with respect to age, gender, marital status, income and smoking status • Predominately white, married males age 68 yrs ± 8 yrs with moderate or higher annual income (> €18,000), non-smokers. • % female: QG 36.4%, controls 23.8%	• 12 men, 40 women • 71% Caucasian • Mean age = 20.82 years (SD = 1.93) • Comparable baseline characteristics with respect to comfort (*F* = 1.46, *P*=.23) and stress (*F*=1.29, *P*=.29) in intervention groups; lower baseline in waitlist controls but not statistically significant • At baseline, even distribution of # of students who scored high on the stress questionnaire for anxiety, insomnia, and depression • Five students who were high on all 3 variables presented as having subclinical stress-related symptoms overall.	• 79 male, 13 female • Mean age (years, mean and SD): SDS 46.2±11.3; TAT 47.6±10.6; QI 47.5±10.5 • 57% of participants were married • 97% completed at least some college • 64% earned annually between $30,000-74,000 • Appeared comparable across study groups but no statistical analysis reported
Random assignment	• Yes, using marked cards	• Yes, but not detailed	• Yes, but procedure not described	• Yes, using design-adaptive allocation • Done by project manager
Intention-to-treat analysis	• No	• Attempted but significant loss of data	• No, unclear if randomized initially • N=4 loss to follow up • N=2 referred for emergency services for extreme stress	• No • N=11 loss to follow up • Reasons=scheduling conflicts, unclear expectations, discomfort with techniques
Intervention(s)	• OEMT (aka V-spread) 20-30 min each x 6 sessions in a 2-3 week period • Sham placebo 20-30 min each x 6 sessions in a 2-3 week period	• All subjects received 2 hours of training on best practices for cardiovascular risk management for 3 sessions over a 2-week period • QG give in 2 90-minute session per week for 16 weeks • Assisted by physician and therapist • Details of QG presented in other publications written in Italian	• HT-mind clearing technique(15-20 min) once/week X 3 weeks • Coaching(15-20 min) once/week X 3 weeks • HT + coaching (30-40 min) once/week X 3 weeks • Wait list control	• Qigong—Emei Zhen Gong style consisting of shaking 5 min, movements 18 min, harvest the energy method 5 min. • TAT—Tapas Fleming protocol practiced daily as needed • Control—SDS through maintenance support groups
Follow up	• Baseline • Post treatment • 6 months follow up	• Baseline • End of training • 16 weeks after training	• Baseline • Before first session • Immediately before third session • 1 week post completion	• At 12 weeks and 14 weeks post-randomization
Outcome measures	• Grip strength • Pain intensity using numerical rating scale (NRS) • Pain limited activity using NRS • Functional level using the Patient Specific Functional Scale (PSFS)	• Functional capacity-six-minute walk test • Body mass index • Total cholesterol • High density lipoprotein • Homocysteine • Ejection fraction	Comfort based on Comfort Theory • Kolcaba online numerical rating scales from 0 to 10; • Expected effects of comfort interventions using *The Healing Touch Comfort Questionnaire (HTCQ), range from* 35 to 210. Stress • Numerical rating scale for comfort for measuring extent of stress "right now."	• Weight change • Psychosocial constructs through structured interviews: • Absorption (Tellegen Absorption Scale) • Expectancy • Social support using Modified Outcomes Study scale • Depression using Center for Epidemiologic Studies Depression Scale • Weight loss history

Study attributes	Nourbakhsh (2007)	Pippa (2007)	Dowd (2007)	Elder (2007)
			• Modified Yarnell *stress test:* checklist of 32 stress-related symptoms with a 5-item response scale measuring degree and frequency of symptoms; range from 32 to 160. • Higher scores =higher stress or comfort	
Blinding	• Subjects and measuring therapist blinded to group assignment • Treating therapist blinded to treatment outcomes	• Not reported, but objective outcome measures used	• No blinded analysis reported • Blinding of students not possible	• Single blinding of personnel weighing the participants • Project manager blinded to participant identity • Project staff arranging visits were blinded to allocation process • Unable to blind participants • Interviews transcribed and coded independently
Results	**Pretest-posttest analysis:** • Treatment group: significant improvement in grip strength (p= 0.04), pain intensity (p= 0.000), functional abilities (p= 0.004), and in pain limited activity (p =0.000). • Placebo group: No significant change (p=0.05) **Between group analysis:** • Significant differences in grip strength (p = 0.03), pain intensity (p = 0.006), pain limited activity (p= 0.025), & functional level (p= 0.003) **Follow up (N=11):** • N=10 (91%) maintained improved function • N=8 (73%) remained pain free for at least six months. • No significant difference between posttest and follow-up measurements for functional activity (mean posttest = 29.266.0, mean follow-up = 27.067.7; p = 0.35); pain intensity (mean posttest = 1.4161.16, mean follow-up = 1.1661.85; p = 0.72); and pain limited activity (mean posttest = 8.8361.02, mean follow-up = 9.1661.19; p = 0.34)	**Baseline:** • Authors stated comparable with respect to six-minute walk, body mass index, total cholesterol, high density lipoprotein and homocysteine levels, and ejection fraction (only available for 17 QG and 7 controls), but statistics not reported • Note: baseline 6 minute walk test for QG group mean 417m ± 107m vs. controls mean 371 m ± 75m **End of training (w/in group analysis):** • QG group walked an average of 114 meters more (27%) than at baseline (*P*<.001). **16 weeks post training:** • QG groups walked 13.7% longer than at baseline (*P*=.008). • Controls showed no significant variation in functional capacity between pre- and post-intervention analyses • No significant differences in biomarkers or EF between treatment and control groups at any follow-up sessions. • 3 drop outs: 2 for lack of interest, one with retinal embolism but all included in analysis • Adverse events in control group: retinal embolism (n=1), deep vein thrombosis (n=1)	52 of 58 data sets were completed: • HT=12; • Coaching= 14; • HT + coaching = 13; • Waitlist= 13. Comfort: • Using Tukey-Kramer analysis, only the coaching group was significantly different ($q_* = 2.7$, $P = .05$) 1 week after the last intervention compared to waitlist. • Improvement in comfort pre to post for each group, with the greatest increases occurring for the HT group at each time point ($P = .0001$); data not collected on waitlist controls Stress • Data on group differences over time unintelligible • At each time point, there were significant decreases in stress-related symptoms (pre- to post) in each group, with the greatest decreases occurring for the HT group at each time point ($P = .0001$). •	**Overall results (Mean ± SD)** • 88% completed study • Comparable compliance with TAT (7.2 ± 2.6 hours), Qigong (5.8 ± 5.8 hours) and SDS (4.8 ± 3.1 hours), but statistics not reported • No significant study-related adverse events. • At 24 weeks, TAT group maintained 1.2 kg more weight loss than SDS (p = 0.09), and 2.8 kg more weight loss than Qigong group did (p = 0.00), only regaining 0.1 kg. • Participants reporting a prior history of recurrent unsuccessful weight loss were more likely to regain weight if assigned to the SDS arm than to QI or TAT (p = 0.03). • TAT was found to be acceptable, easy to use, portable, engaging and useful. • Qigong was found to be promising particularly for overall well-being, but too brief and socially unaccepted.
Authors' conclusions	• Study demonstrated both clinically and statistically significant improvements in grip strength, pain intensity, function, and activity tolerance in subjects with chronic LE after OEMT treatment compared with placebo. • These findings suggest that OEMT could be a viable, effective, and efficient alternative treatment for symptoms of chronic LE.	• QG was well tolerated with no serious adverse effects, and well liked with no complaints of heart rate related symptoms and no arrhythmic episode was diagnosed • QG may induce significant and long-lasting improvement in functional capacity in persons with chronic AF and preserved ventricular function	• HT mind clearing had better immediate results on stress and comfort in college students seeking help with stress • Coaching had better carryover results on both outcomes. • Findings for the combined treatment group were inconsistent. • HT mind clearing component had immediate	• Study suggests a potential role for TAT in weight-loss maintenance programs and further research is warranted. • Further study of Qigong is not supported without modification of the protocol.

Study attributes	Nourbakhsh (2007)	Pippa (2007)	Dowd (2007)	Elder (2007)
	• Additional research is needed with larger sample sizes to study the effects of OMET on somatic pain and dysfunction associated with other pathologies, to explore the mechanism of action with OMET and to establish consistency of technique across multiple practitioners.	• *"In conclusion, in patients with chronic AF and preserved ventricular function, a training program based on traditional Chinese medicine showed a significant improvement in physical capacity. This finding might have relevant implica-tions for cardiac patients and could expand the range of those who benefit from rehabilitation interventions. Further research is warranted."* **Limitations** • Comparison to trials of other types of isotonic exercise not possible because different outcome measurements were used i.e. objective measures of peak oxygen uptake and resting heart rate vs. 6 minute walk test • Support from a local nonprofit for travel, reminders and counseling may have affected outcomes of QG group	effects, but continuation of these effects was compromised by the absence of take-home self-care strategies.	
TAP notes	• Med use (i.e. for pain or inflammation) not reported • Pain may influence grip strength • Cause of LE (eg. inflammation, tissue degeneration, scar tissue) may influence findings • Mechanism of effect of OEMT unclear • PSFS intended to measure changes within the individual, not between groups • Small sample size • Significant loss to follow up	• Small sample from single center • Recruitment sample selection details incomplete • No power calculations • Limited outcomes used • Randomization and blinding not reported	• Has the Yarnell stress test been validated? • Poor editing • Many design limitations: underpowered, ITT unclear, no blinding, incomplete reporting of randomization, use of outcome measures of questionable validity based on questionable theoretical underpinnings eg. the Comfort Theory.	• Supported by a grant (R21 AT01190-02) from NCCAM • Phase III study underway (NCT00526565; see Table 2)

Table 5 (continued)

Study attributes	Astin (2006)	Wells (2003)	Kessler (2002)	Abbott (2001)
Study objective	To assess the efficacy of distant healing for human immunodeficiency virus (HIV)	To determine the efficacy of Emotional Freedom Technique (EFT) for reducing anxiety and self avoidance behavior in persons with phobias of small animals (spider, mouse, rat or roach)	To measure the effect of Thought Field Therapy (TFT) on perpetrators of domestic violence with PTSD	To assess the efficacy of healing in the treatment of chronic pain.
Study size	N= 124 (42 controls, 36 nurse untrained healers, 46 professional healers)	• N=46 (18 individual EFT, 17 DB) • Eligible volunteers who responded after treatment assignment were assigned to a separate group EFT intervention (N=11)	• N=45 (17 TFT + shortened CBT, 16 CBT) • Pre-assigned to one of five CBT groups of 8-12 individuals by agency staff based on client's work schedule	N= 105 (53 treatment, 52 controls)
Perspective	Prospective	Prospective	Prospective	Prospective
Recruitment source	• 150 subjects from the San Francisco Community Consortium	• Volunteers from community advertisements (N=70) • Telephone screened using structured interview	• N=50 convenience sample of referrals by courts for breaking domestic violence laws or • Volunteers to the local domestic violence agency	• 650 patients who had attended the Pain Management Clinic at the Royal Devon and Exeter Hospital • 205 responded, 73 excluded based on criteria
Inclusion criteria	• Ages 18-65 • CD4+ T-cells < 200/mm^3 • At least 1 AIDS-defining opportunistic infection • Currently receiving any combination antiretroviral therapy	• Age ≥ 18 years • Symptoms matching DSM-IV (APA 1994) criteria for specific phobia • Untreated • Agree to be contacted for follow-up testing	• Adult males • Currently participating in local domestic violence program • Signed consent	• Willingness to participate • Frequent or persistent pain of at least 6 months duration • Intensity of pain rated as ≥ 25 on a visual analogue scale (VAS) • Informed consent • Age 18 to 75 years • Approval of general practitioner • Ability to attend all healing sessions
Exclusion criteria	See above	• Subjective units of distress (SUDS) level < 5 on the Behavioral Approach Task (BAT), i.e. excluding those with symptoms that were not disabling	• Invalid scores on the atypical response (ATR), response level (RL) and Inconsistent response (INC) scales of the Trauma Symptom Inventory (TSI)	• Previously received any form of spiritual healing
Characteristics of study subjects	Comparable baseline characteristics with respect to: • Medical facility utilization (numbers of primary clinic, referral and ER visits, and inpatient hospitalizations) • Mood (profile of Mood (POM) state at 6 mo and 12 mo.) • Quality of Life (Functional Assessment of Human Immunodeficiency Virus (FAHI) score change at 6 mo and 12 mo) • Illness severity (number of AIDS illnesses prior to, acquired during or resolved during study measured at 12 mo)	• 43 females, 3 males • Mean age=39.6 years (range 19-72 years) • Duration of phobia: N=23 from 3 to 50 years (mean=20 years); N=23 "for as long as they can remember." • Comparable baseline characteristics between groups with respect to age, mean pre-treatment confidence level, or any pre-test value of any outcome measure used	• All male • Various ethnicities • Mean age=34.60, SD=8.87, range 20-52 • Median gross income ranged $20,000 to $29,000 • Unclear comparability of baseline characteristics with respect to ethnicity, gross income, educational level, substance use, childhood mistreatment and prescription drug use	• Comparable baseline characteristics with respect to: age range, gender breakdown, employment status, healing beliefs, site of pain, origin of pain, or use of drugs • Subjects represented a mix of male and female adults ages 44.8 yrs to 61.7 yrs, not employed with moderate-severe chronic pain lasting for several years • Baseline data for outcome measures did not differ between groups or between baseline 1 or baseline 2
Random assignment	• Subjects grouped into cohorts of 12-15 persons enrolled within a specified 2-week period • Computer-generated random assignment	Yes, but procedure not described	• Partially, description is confusing • 5 smaller groups randomly assigned to either treatment or control group • Covariance ANOVA used to reassign groups prior to treatment to create uniformity of	• All eligible subjects first ranked by pain intensity computer-generated block (2 by 2) randomization method from top to bottom • Second randomization to healing or control group using a computer-generated block (2

Study attributes	Astin (2006)	Wells (2003)	Kessler (2002)	Abbott (2001)
			baseline testing between two groups.	by 2) method. • Random code sealed and locked
Intention-to-treat analysis	• Not explicitly stated • Differences in missing data (= CD4-count data at 12 mo) between treatment arms, by age and by initial CD4 count were analyzed	• No • N=14 loss to follow up reasons=relocation, reluctance	• No • Loss to follow up: o Treatment=8 (36%) (invalid score-1, graduated-4, discharged-1, hospitalized-1, arrested-1) o Control=9 (32%) (invalid score-4, graduated-3, discharged-2)	• Modified =Data were analyzed for all patients who had received at least 4 weeks of treatment
Intervention(s)	• Self-identified distant-healing practitioners with at least 50% of professional time spent doing healing work, at least 10% of practice devoted to distant healing and experience with at least 20 patients with AIDS (N=50) • Nurses without prior distant healing/energy work experience, with at least 5 years experience as RN and experience with at least 10 HIV patients (N=100) • Distant healing treatment every other week from a nurse or healer for a total of 10 weeks healing=~60 hours of healing • Control =no treatment	• EFT- one 30 min. session • DB- one 30 min. session • Group EFT—one 75 min. session	• Control= Group CBT—30 min/week x 3 weeks • Treatment= TFT + shortened group CBT—30 min/week x 3 weeks • Researcher trained in TFT Level I, II, III.	Predefined protocols for patient-healer interaction Part 1: • Face-to-face healing (minimal or non-contact) • Simulated healing (control) Part 2: • Distant healing • No healing (control)
Follow up	• Baseline • 6 months • 1 year	• Baseline • 6 months post treatment (EFT mean = 7.6 months, range 6-9 months; DB mean = 8.1 months, range 7-9 months)	• Pre-test baseline • Post 3rd weekly session • One month follow up	• Baseline 1= at initial interview • Baseline 2= first day of trial • After each trial=MPQ and VASs, subjective experiences during therapy only • Week 4=All outcome measures • Week 8= All outcome measures
Outcome measures	**Primary outcomes:** • Medical facility utilization • Mood (POM state) • Quality of Life (FAHI version 4) • Illness severity **Secondary outcomes:** • HIV RNA • Absolute CD4+ T lymphocyte count • Indicators of anti-retroviral therapy toxicity (triglycerides, total cholesterol, high-density lipoprotein (HDL) cholesterol, alanine transamine (SLT), aspartamine transamine (AST), alkaline phosphatase)	• Level of avoidance (BAT) • Fear using the Brief Standard Self-Rating for Phobic Patients • SUDS when imaging the animal • SUDS during BAT • Pulse rate • Pre-treatment confidence rating (1 point scale)	• Anxious arousal (AA) scale • Intrusive experiences (IE) scale • Defensive avoidance (DA) scale	• Total pain rating index (PRIT) score of the McGill Pain Questionnaire (MPQ) at week 8 • VASs for pain intensity • SF36 quality of life scale • Hospital Anxiety and Depression (HAD) scale • MYMOP (Measure Yourself Medical Outcomes Profile)
Blinding	• Subjects blinded to treatment • Project coordinator and research assistant blinded to treatment allocation	• Assessors blinded to group assignment	• Assessor not blinded to intervention • Assessor performed intervention and data collection and analysis • Unable to blind subjects to treatment	• Participants and investigators blinded to treatment group assignment • Healers, simulated healers and PI not blinded to group assignment
Results	• No significant between-group differences on any primary outcomes, except a borderline reduction in inpatient hospitalizations in controls vs. professional healer group (P=0.07)	Based on N=21 (12 EFT, 9 DB) **Pretest-posttest analysis:** For immediate effect: • EFT showed greater improvement than DB on BAT [$F(1,33) = 6.63$, $p < .02$]; SUDS	**Pre-post treatment analysis:** • For AA, there was a main effect for time $F(2,62) = 3.390$, $p = .04$, but no significant time by treatment interaction, $F(2,62) = 1.480$, $p = .24$	• No significant differences in any outcome measure found between baselines 1 or 2 for any group • Significant decreases ($P \leq 0.05$) in MPQ PRIS from baseline to week 8 for both

Study attributes	Astin (2006)	Wells (2003)	Kessler (2002)	Abbott (2001)
	• Statistically significant reduction in CD4+ count data at 6 mo in nurse healer group vs. controls (*P*=0.02) but not significant at 12 mo. • Significant reduction in mean triglyceride levels at 12 mo in nurse healer group vs. controls (-82.6 mg/dL vs. 8.6 mg/dL, *P*=0.028) **Missing data**: controls, 14; nurse healers, 22; healers, 22 • No difference in missing data rates between arms (X^2=3.51, *P*=0.17) • Neither age (*P*=0.54) nor CD4 (*P*=0.21) affected likelihood of absent 12-month values **Blinding** • At 6 mo, 72% of nurses group, 82% of healer group vs. 51% of controls believed they were in one of the treatment arms (*P*=0.02), but no longer significant at 12 mo.	imagined *F*(1,33) = 8.84, *p* < .005]; SUDS during BAT *F*(1,33) = 7.34, *p* < .02]; and Fear questionnaire *F*(1,33) = 10.53, *p* < .02] • No statistically significant difference in the amount of decrease in pulse rate between treatment interventions *F*(1,33) = .01, n.s. • Large effect sizes (Cohen's *d*) observed for BAT (1.24 *SD*), SUDS Imagined (1.42 *SD*), SUDS during BAT (1.30 *SD*) and the Fear questionnaire (1.54 *SD*) For long-term effect: • EFT showed greater sustained improvement than DB on BAT [*F*(1,19) = 6.81, *p* < .02] • No statistically significant differences between interventions on SUDS Imagined [*F*(1,19) = 0.11, n.s.]; SUDS during BAT *F*(1,19) = n.s.]; or the Fear questionnaire *F*(1,19) = 0.86, n.s.]. • Mixed effect sizes (Cohen's d) observed for BAT (1.63 *SD*); SUDS Imagined (0.02 *SD);* SUDS during BAT (0.74 *SD*); Fear questionnaire (0.58 *SD).*	• For IE, there was no main effect for time nor a time by treatment interaction (all *p* > .05) • For DA, there was a main effect for time and a marginal effect for time by treatment interaction, but statistical data not reported **Comparison of overall mean scores and SD:** • N=21 controls, 24 treatment • Considerable overlap between treatment and control groups in all three outcomes	healing group [32.8 (95% CI, 28.5±37.0) to 23.3 (95% CI, 16.8±29.7)] and simulated healing group [33.1 (95% CI, 27.2±38.9) to 26.1 (95% CI, 19.3±32.9)] in part I; and for the control group [31.0 (95% CI, 25.8± 36.2) to 21.0 (95% CI, 15.7±26.2)] in part II • No statistically significant differences between healing and control groups in either part • Significantly more unusual experiences were reported by the healing group than controls in part I (X^2=15.6, P ≤ 0:001) and in part II (X^2= 5.12, P ≤ 0:05) where there were also significantly more individuals reporting unusual experiences (X^2 =9.3, P ≤ 0:01) • Significant perceived improvements in pain occurred to a similar extent in the healing and control groups
Authors' conclusions	• *"Though we cannot make an overall determination regarding the efficacy of distant healing as a healing modality based on the findings of the present study, distant healing or prayer from a distance does not appear to improve selected clinical outcomes in HIV patients who are on a combination antiretroviral therapy."*	• On important behavioral tasks such as level of avoidance, evidence suggests that EFT has a significant effect that lasts 6-9 months in persons with at least moderate phobia severity. • Lack of significance or effect of other measures may be due in part to underpowered study; to achieve a *d* = 0.75, a sample size of 30 in each group would be needed to achieve P=80%, α = .05 • Limitations: potential investigator bias, insufficient power, and participant expectation • Results should be confirmed in future study • Future research should address why EFT works and the effectiveness of EFT compared to therapist-directed exposure therapy	• The results do not support the use of TFT as an effective component of therapy in reducing AA, IE or DA, common symptoms of PTSD. • Future research should focus on comparable group matching at baseline and longitudinal studies of at least a year on larger and more diverse populations. • Analysis of the components of each TFT protocol is needed to test efficacy of prescribed points with objective testing to confirm changes effected by TFT protocols	• The results do not demonstrate that face-to-face healing is more effective than simulated healing nor that distant healing is more effective than no healing. • Perceived benefits of improvements in pain and satisfaction with healing sessions may be due to "non-specific"/placebo effects of the patient-therapist encounter eg. relaxation, quality time, hope, trust or expectation • Future research should address these factors under experimental conditions
TAP notes	• Large amounts of missing data which limited power • Missing data analyzed separately • Healers reported that use of multiple healers may adversely affect healing process	• Significant loss to follow up	• No power calculations • No blinding • Inadequate randomization • Researcher is also the treatment provider, leading to potential bias in data collection and analysis • Significant loss to follow up	

VA TECHNOLOGY ASSESSMENT PROGRAM

Mission Statement

To enhance the health of Veterans and the nation by providing and fostering technology assessment for evidence-based health care

Values

Integrity and pride in the work that we do

Quality products that are clinically valid and methodologically transparent

Objectivity in evaluating and presenting research evidence

Commitment to continuous quality improvement and to the guiding principles of evidence based practices

Flexibility in responding to changes in VA and the larger healthcare environment

Innovation in designing products and their dissemination to best meet VA's needs

Accessibility of products and services